



Food and Drug Administration
Rockville MD 20857

MAR 3 1998

TRANSMITTED BY FACSIMILE

Robert W. Pfeifer, M.S., R.Ph.
Manager, Medical and Regulatory Affairs
Roxane Laboratories, Inc.
P.O. Box 16532
Columbus, Ohio 43216-6532

Re: **NDA 18-651**
Marinol (dronabinol) Capsules
MACMIS ID #6225

Dear Mr. Pfeifer:

This letter is in reference to Roxane Laboratories, Inc.'s (Roxane) submission dated November 11, 1997, of promotional materials under cover of Form FDA 2253 for Marinol (dronabinol) Capsules. This submission consisted of a promotional labeling brochure (RX-1879). The Division of Drug Marketing, Advertising, and Communications (DDMAC) considers material in this brochure to be false or misleading and the dissemination to violate the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

On the front cover of the brochure, Roxane asks the question "[w]hat is an important defense against progression of AIDS?" Roxane then presents the brand and established name of Marinol at the bottom of the page. This presentation suggests that Marinol is effective in halting the progression of aids. However, the Indications and Usage section of the approved product labeling for Marinol states that it is indicated "for the treatment of anorexia associated with weight loss in patients with AIDS" There is no evidence that the use of Marinol halts the progression of AIDS. Any implication by Roxane that the use of Marinol alters the progression of AIDS is false or misleading.

Roxane should immediately suspend all promotional activities and materials that convey or contain the violative claims or information identified in this letter. Roxane should submit a written response to DDMAC on or before March 18, 1998, listing all the promotional materials that contain the same or similar violative promotional claims and when the use of these violative materials will be or was discontinued.

Roxane should address its correspondence to 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.

Mr. Robert W. Pfeifer
Roxane Laboratories, Inc.
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Please reference MACMIS ID #6225 in addition to the NDA number in future correspondence concerning this issue.

Sincerely,

Stephen W. Sherman, JD, MBA
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications