DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

JUL 23 1998

TRANSMITTED VIA FACSIMILE

Lynn A. DeVenezia-Tobias
Program Manager, Drug Regulatory Affairs
Hoffman-LaRoche Inc.
Bldg. 1\2
340 Kingsland Street
Nutley, NJ 07110-1199

RE: **NDA 20-811**
Acular PF (ketorolac tromethamine ophthalmic solution) 0.5%
MACMIS ID # 6826

Dear Ms. DeVenezia-Tobias:

This letter is in reference to Hoffman-LaRoche Inc.'s (Roche) submission of promotional materials under cover of Form FDA 2253, dated June 1, 1998, for Acular PF (ketorolac tromethamine Ophthalmic Solution) 0.5%. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed the submitted brochure (no identifying number) and concludes that it is misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Fast Relief

In the brochure, Roche claims that Acular PF provides patients with "fast relief" and suggests that healthcare providers "prescribe Acular PF for fast relief from ocular pain and photophobia following incisional refractive surgery." DDMAC considers this claim to be misleading because Roche has not provided context for its claim of "fast relief."

Roche should instruct its sales force to immediately discontinue the use of the above brochure, and any other promotional materials that make similar misleading claims for Acular PF. Roche should respond to DDMAC regarding this violation by letter no later than August 6, 1998. In its response, Roche should submit a list of the promotional materials it has discontinued.

If you have any questions, please contact me or by facsimile at (301) 827-2831, 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 Roche that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 6826 and NDA 20-811.

Sincerely,

/S/

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