DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 18 1997

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 19-700**
Acular (ketorolac tromethamine) 0.5% Sterile Ophthalmic Solution
MACMIS ID # 5700

Dear Ms. DeVenezia-Tobias:

This letter is in reference to Hoffman-LaRoche Inc.'s (Roche) two submissions of two separate promotional "Dear Dr." letters under cover of Form FDA 2253, dated June 17, 1997, for Acular (ketorolac tromethamine) 0.5% Sterile Ophthalmic Solution. The Division of Drug Marketing, Advertising and Communications (DDMAC) considers the letters to be false and/or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Misleading Claim of Superiority

In the first "Dear Dr." letter, Roche states:
"As you know, many seasonal allergy patients who visit your office may be taking a systemic antihistamine. This raises the questions about the additive value of a topical antihistamine for such patients."

"I hope you agree that Acular Solution makes good sense for fast, targeted, ocular itch relief due to seasonal allergic conjunctivitis--even for patients already taking systemic antihistamines."

DDMAC considers that these statements imply Acular is more effective than ocular antihistamine products for treating ocular itching from seasonal allergic conjunctivitis in patients who are taking systemic antihistamines. Roche has not provided support for this claim. Claims of superiority generally require substantial evidence, (i.e., two adequate and well-controlled, head-to-head supporting studies).

Roche should instruct its sales force to immediately discontinue the use of the above letters, and any other promotional materials that make false and/or misleading claims for Acular. Roche should respond to DDMAC regarding these violations by September 2, 1997. In its response, Roche should state which promotional materials it has discontinued.

If you have any questions, please contact me or by telephone at (301) 827-2831, 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 # 5700 and NDA 19-700.

Sincerely,

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