DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 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 # 6022

Dear Ms. DeVenezia-Tobias:

This letter is in reference to Hoffman-LaRoche Inc.'s (Roche) submissions (2) of promotional materials under cover of Form FDA 2253, dated October 20, 1997, for Acular (ketorolac tromethamine) 0.5% Sterile Ophthalmic Solution. The Division of Drug Marketing, Advertising and Communications (DDMAC) considers these materials to be false and/or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Fair Balance Information

DDMAC considers the submitted promotional materials[1] to be lacking in fair balance or otherwise misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations because the materials fail to present any information relating to the product's side effects and contraindications, or other risk information. Roche should present balancing risk information in a manner reasonably comparable in prominence and readability to the presentation of information relating to the effectiveness of the drug.

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

[1] The promotional materials are: an Acular New Indication Video Billboard, and an Acular Postoperative Inflammation Convention Board.

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 # 6022 and NDA 19-700.

Sincerely,

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