DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV - 3 1998

TRANSMITTED VIA FACSIMILE

Ellen R. Westrick
Director, Office of Medical/Legal
Merck & Co., Inc.
West Point, PA 19486

RE: **NDA 20-869**
Cosopt (dorzolamide hydrochloride - timolol maleate ophthalmic solution)
MACMIS # 7209

Dear Ms. Westrick:

This letter is in reference to Merck and Co., Inc.'s (Merck) promotional materials for Cosopt (dorzolamide hydrochloride - timolol maleate ophthalmic solution). The Division of Drug Marketing, Advertising and Communications (DDMAC) has identified, through its surveillance activities, a news report produced for Merck that is false and/or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Promotional of Unapproved Use

On October 26, 1998, DDMAC identified a news report titled "Studies Demonstrate Efficacy Of Cosopt, Merck's Combination Treatment For Reducing Intraocular Pressure In Glaucoma Patients" that was presented at the WWW site "newstream.com/98-408.shtml." In the news report, Merck stated that "among the results of three recently published studies in this month's (October 1998) issue of *Ophthalmology*," findings in one study showed that in a clinical trial, Cosopt was an effective therapy in "patients with open-angle glaucoma who were not currently receiving treatment."

DDMAC is concerned that Merck reported the effectiveness of Cosopt as a first-line therapy when Cosopt is indicated as a second-line therapy in patients with open-angle glaucoma **who are insufficiently responsive to beta-blockers (emphasis added)**, and that Merck did not disclose this fact in the news report. DDMAC considers this news report to be labeling and, thus, a promotion of Cosopt for a use that has not been shown to be safe and effective.

Fair Balance

> In the news report, Merck reported that the drug was effective, but failed to present any information relating to the product's side effects and contraindications, or other risk information. This required balancing risk information should be presented in a manner reasonably comparable in prominence and readability to the presentation of information relating to the effectiveness of the drug.

Because of the above violations, DDMAC requests that Merck immediately cease the dissemination of this violative news report. Merck should respond to DDMAC regarding this violation by November 17, 1998, providing the date it ceased the dissemination of the promotional material.

If you have any questions, please contact me 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. DDMAC reminds Merck that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7209 and NDA 20-869.

Sincerely,

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