DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 23 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 # 6527

Dear Ms. Westrick:

This letter is in reference to Merck and Co., Inc.'s (Merck) submission of a journal advertisement under cover of Form FDA 2253, dated March 23, 1998, for Cosopt (dorzolamide hydrochloride - timolol maleate ophthalmic solution). The Division of Drug Marketing, Advertising and Communications (DDMAC) considers the advertisement to be false and/or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Preapproval Promotion

Merck submitted a copy of a "coming soon" journal advertisement from the March 15, 1998, issue of Ophthalmology Times. At the time of publication of the advertisement, Cosopt was an unapproved drug (Cosopt was approved for use on April 7, 1998). The advertisement depicts the artistic image of an eye, presents the proprietary and established names of the drug, and claims that the drug is "built on a legacy of proven therapies." DDMAC considers that Merck's phrase "legacy of proven therapies" refers to its approved products Timoptic (timolol maleate) and Trusopt (dorzolamide hydrochloride) that are the basis for the new combination product. Thus, Merck promoted Cosopt prior to its approval by making representations about the drug name and its intended use.

As you know, a sponsor of an unapproved drug can choose one of two types of advertising: (1) an advertisement that announces the name of the anticipated new product, but **contains no representation or suggestion about the use of the product** (emphasis added); or (2) an advertisement that does not name the new product but names the sponsoring company with a statement to the effect that the company is doing research in the medical area in which the drug will be used.

Merck should respond to DDMAC regarding this violation by May 7, 1998.

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 # 6527 and NDA 20-869.

Sincerely,

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