DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FDA

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

FEB 21 1997

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

RE: **NDA 20-408**
Trusopt (Dorzolamide Hydrochloride Ophthalmic Solution)
MACMIS # 5156

Dear Ms. Westrick:

This letter is in reference to Merck and Co., Inc.'s (Merck) submission, dated January 10, 1997, of promotional materials under cover of FDA Form 2253 for Trusopt (Dorzolamide Hydrochloride Ophthalmic Solution). This submission included a sales aid/print materials holder identified as L2259-1196. The Division of Drug Marketing, Advertising and Communications (DDMAC) regards the promotional material to be false and/or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

#1 Prescribed Anti-glaucoma Agent

> On the front cover of the sales aid, Merck claims that Trusopt is the #1 prescribed anti-glaucoma agent, and cites data from the September 1996 IMS America, Ltd. for support of this claim. DDMAC has reviewed the supporting data and concludes that Trusopt is the most prescribed intraocular pressure reducing agent. However, DDMAC is not aware of any drug products that prevent or eliminate glaucoma. Thus, we consider the term "anti-glaucoma" to be misleading and request that Merck delete the term "anti-glaucoma." DDMAC would not object to Merck claiming that Trusopt is the number one prescribed intraocular pressure lowering agent or that it is the number one prescribed carbonic anhydrase inhibitor.

Merck should cease immediately using this sales aid and all other materials that make the above described false and/or misleading claim. Merck should respond to DDMAC regarding this issue by March 7, 1996.

If you have any questions, please contact me by telephone at (301) 827-2831, 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.

In all future correspondence regarding this matter, please refer to MACMIS # 5156 and NDA 20-408.

Sincerely,

Warren Rumble

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

trusopt.nov

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| Drafted: | Rumble | 02-14-97 |
| Concur: | Sherman | 02-18-97 |
| Concur w/ comment: | Abrams | 02-20-97 |

WR 2/21/97

cc. HFD-40 NDA 20-408
HFD-40 chron/Rumble/Abrams
HFD-550 NDA 20-408
HFD-550 CSO-Holmes/Div Dir-Chambers

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| MACMIS ID# | 5156 |
| MACMIS Type Code: | LTTR |
| MACMIS Action Code: | VIOL |
| 2253 ID#: | 48209 |
| Material ID#: | L2259-1196 |
| Close Out: | NO |
| Due Date: | March 7, 1997 |

FOI Status- Releasable