



FOI

Food and Drug Administration
Rockville MD 20857

AUG 20 1998

TRANSMITTED VIA FACSIMILE

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 # 6896

Dear Ms. Westrick:

This letter is in reference to Merck & Co., Inc.'s (Merck) submissions, dated July 6 and 10, 1998, of promotional materials under cover of Form FDA 2253 for Trusopt. The submissions included a card identified as 981438(1)-07-TRU, a Dear Doctor letter and "Data available package TRU14(1), and an advertisement from the July 1, 1998, issue of the Ocular Surgery News entitled "An open letter to the ophthalmologic community" and identified as 984878(1)(0004)-TRU. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these promotional materials and concluded that they are false or misleading under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Misleading Claims of Safety

In both the advertisement and promotional labeling, Merck claims that the incidence of stinging reported with the use of Trusopt is 11.6%. In the Data Available Package, Merck claims that the most common ocular experience with the use of MK-507 (Trusopt) were burning/stinging at 3.5%. However, these claims are inconsistent with the approved product labeling that states "in clinical studies, the most frequent adverse events associated with Trusopt were ocular burning, stinging, or discomfort immediately following ocular administration (approximately one-third of patients). The approved product labeling for Trusopt does not distinguish between the ocular discomfort symptoms experienced in clinical trials. Further, because the terms ocular burning, stinging, and discomfort are frequently interchanged in reporting adverse events, Merck should report the ocular discomfort seen with the use of Trusopt consistent with the approved product labeling.

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Merck should immediately cease the dissemination of these violative promotional materials and all similar promotional materials that make false or misleading claims regarding the safety of Trusopt.

Merck's written correspondence regarding this matter should be received by DDMAC no later than September 3, 1998.

Please direct your correspondence to undersigned by facsimile (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 # 6896 and NDA 20-408.

Sincerely,

/S/

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