DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-869/S-020

Merck & Co., Inc.
Attention: Mary Beth Wigley
Manager, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Ms. Wigley:

Please refer to your supplemental new drug application dated March 5, 2004, received March 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cosopt (dorzolamide hydrochloride-timolol maleate ophthalmic solution).

We acknowledge receipt of your submissions dated August 6, and September 30, 2004. Your submission of September 30, 2004, constituted a complete response to our July 26, 2004, action letter.

This supplemental new drug application provides for: the relocation of information within the adverse reactions section of the labeling; a revised product description; a revised Pediatric Use section, and a revised storage statement.

We completed our review of this supplemental new drug application as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 30, 2004.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301)827-2019.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Division Director
Division of Anti-Inflammatory, Analgesic, and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Wiley Chambers

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