DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-869/S-030

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

Dear Ms. Wigley:

Please refer to your supplemental new drug application dated February 8, 2006, received February 9, 2006, 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 submission dated April 10, 2006.

This "Changes Being Effected" supplemental new drug application provides for changes to the Patient Package Insert (PPI) for COSOPT.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on February 8, 2006.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the PPI submitted on February 8, 2006).

Submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical to the enclosed labeling text/submitted labeling text date February 8, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
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/

Janice Soreth

8/9/2006 02:09:01 PM