DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-869/S-022

Merck & Co., Inc.
Attention: Mary Beth Wigley
Manager, Regulatory Affairs
770 Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Ms. Wigley:

Please refer to your supplemental new drug application dated August 9, 2004, received August 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for COSOPT (dorzolamide hydrochloride-timolol maleate ophthalmic solution).

We also acknowledge receipt of your submissions dated September 8, and 23, 2005.

Your submission of September 23, 2005, constituted a complete response to our September 7, 2005 action letter.

This supplemental new drug application provides for the introduction of a Patient Package Insert (PPI) and a Patient Support Glaucoma Booklet (PSGB) 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 for the PPI.

The photograph on page 3 of the proposed Patient Support Glaucoma booklet should be revised in the next labeling supplement. The photograph should represent the severely reduced visual field with generalized constriction and an arcuate scotoma. The representation of the arcuate scotoma is inaccurate. The arcuate scotoma would be less dense and less well-defined on the left side of the image and occur approximately 15° from center.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-869/S-022**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Infective and Ophthalmology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

Attachment: Patient Package Insert

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

12/9/2005 04:14:13 PM