**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-869/S-026
NDA 20-869/S-028

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

Dear Ms. Wigley:

Please refer to the following supplemental new drug applications, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for COSOPT™ (dorzolomide hydrochloride-timolol maleate):

| Supplement Number | Letter Date | Received Date |
|---|---|---|
| S-026 | June 1, 2005 | June 2, 2005 |
| S-028 | October 25, 2005 | October 26, 2005 |

We acknowledge receipt of your December 8, 2005, and April 13, 2006, amendments to S-026, and your April 10, 2006, amendment to S-028.

Your April 13, 2006, amendment to S-026 constituted a complete response to our December 1, 2005, action letter for that supplement.

Supplement 026 provides for changes to the **INSTRUCTIONS FOR USE** section of the package insert and changes to the bottle and cap labels.

Supplement 028 provides for changes to the **PRECAUTIONS** and **HOW SUPPLIED** sections of the labeling, as well as incorporates the changes to the **INSTRUCTIONS FOR USE** section as proposed in Supplement 026.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the labeling text submitted on October 25, 2005, (package insert), and June 1, 2005, (bottle and cap labels).

The final printed labeling (FPL) must be identical to the enclosed draft labeling (package insert submitted October 25, 2005, and bottle and cap labels submitted June 1, 2005).

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

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, 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

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

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/s/

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Janice Soreth

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