DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-463/S-027

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 application dated December 2, 2005, received December 5, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TIMOPTIC in OCUDOSE (timolol maleate ophthalmic solution) 0.25% and 0.5%

We acknowledge receipt of your submission dated April 10, 2006.

This "Changes Being Effected" supplemental new drug application provides for changes to the **PRECAUTIONS** sections of the package insert labeling.

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 December 2, 2005.

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 Michael Puglisi, Project Manager, at (301) 796-0791.

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/

Wiley Chambers
6/5/2006 05:02:40 PM
For Janice Soreth, MD