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APPLICATION NUMBER:

18-086 / S-060

MEDICAL REVIEW

Medical Officer's Review NDA 18-086
Amendment

NDA 18-086
S-060/AF

Submission Date: June 27, 2003
Received Date: June 24, 2003
Review Date: November 24, 2003

Sponsor:

Merck & Co., Inc.
P.O. Box 4, BLA-20
West Point, PA 19486

Virginia G. Snyder
(484) 344-7984

Drug:

Timoptic Ophthalmic Solution (Timolol
Maleate)

Pharmacologic Category:

beta-adrenergic blocker

Submitted:

Amendment to a pending application with electronic labeling of the package insert to add pH and osmolarity to the label in the DESCRIPTION section and a full description of the product in the HOW SUPPLIED section.

Following is the labeling submitted by the company. Reviewer recommended deletions are noted by ~~strikeout~~ and additions by double underline within the review.

WITHHOLD 9 PAGE(S)

Draft labeling

Medical Review