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***APPLICATION NUMBER:***

**20-330 / S-017**

**MEDICAL REVIEW**

Medical Officer's Review NDA 20-330  
Labeling Supplement

**NDA 20-330  
S-017**

**Submission Date:** June 20, 2003  
**Received Date:** June 33, 2003  
**Review Date:** October 30, 2003

**Sponsor:**

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

Virginia G. Snyder  
(484) 344-7984

**Drug:**

Timoptic-XE (timolol maleate ophthalmic  
gel forming solution) 0.25% and 0.5%

**Pharmacologic Category:**

beta-adrenergic blocker

**Submitted:**

Special Supplement-Changes Being Effected with electronic labeling of the package insert to add pH and osmolarity to the label in the DESCRIPTION section and to revise the HOW SUPPLIED section to provide descriptive information of the containers and fill size.

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

**WITHHOLD 13 PAGE(S)**

Draft Labeling

Medical Review

Jennifer D. Harris, MD  
Medical Officer

cc:  
NDA 20-330  
HFD-550/Div Files  
HFD-550/CSO/Puglisi  
HFD-550/CHEM/Lu  
HFD-550/MO/Harris  
HFD-550/SMO/Chambers

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/s/

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Jennifer Harris  
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11/21/03 02:19:43 PM  
MEDICAL OFFICER