

Medical Officer's Review of NDA 19-845 SE-020/20-963 SE-010
Review #2

NDA 19-845 SE-020
NDA 20-963 SE-010
Medical Officer's Review #2

Submission Date: June 6, 2007
Review Completed: June 7, 2007

Trademark:

Betoptic S
Timolol GFS

Generic Name:

betaxolol hydrochloride ophthalmic suspension 0.25%
timolol maleate ophthalmic gel forming solution 0.25% and 0.5%

Sponsor:

Alcon Research, Ltd.

Authorized U.S. Agent:

Angela C. Kothe, OD, PhD
Director Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134

Telephone 817-551-4933
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Pharmacologic Category:

beta-blocker

Reviewer's Comments:

The revised labeling which follows is based on previous review, discussion with the applicant, and an updated insert transmitted by the applicant on June 7, 2007.

The applicant has accepted all changes to the labeling as requested by the Division. The applicant has also made some minor editorial changes. This labeling is acceptable.

17 Page(s) of Draft Labeling has been Withheld in Full as B4 (CCI/TS)
immediately following this page

M.O. Review #2

NDA 19-845 SE-020/20-963 SE-010 Betoptic S (betaxolol hydrochloride ophthalmic suspension) 0.25%
Timoptic GFS (timolol maleate ophthalmic gel forming solution) 0.25% and 0.5%

Recommendations:

It is recommended that **NDA 19-845 S-020 and NDA 20-963 S-010** be approved with the labeling submitted.

Sonal D. Wadhwa, MD
Medical Officer

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NDA 19-845 SE-020/20-963 SE-010 Betoptic S (betaxolol hydrochloride ophthalmic suspension) 0.25%
Timoptic GFS (timolol maleate ophthalmic gel forming solution) 0.25% and 0.5%

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/s/

Sonal Wadhwa
6/7/2007 02:37:34 PM
MEDICAL OFFICER

William Boyd
6/8/2007 08:51:19 AM
MEDICAL OFFICER