DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-907/S-025

Bausch & Lomb Incorporated
Attention: Joseph B. Hawkins
Director, Regulatory Affairs
8500 Hidden River Parkway
Tampa, FL 33637

Dear Mr. Hawkins:

Please refer to your supplemental new drug application dated May 5, 2006, received May 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OptiPranolol® (metipranolol hydrochloride ophthalmic solution), 0.3%.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate (b)(4)-------- line, ((b)(4) Room (b)(4)) for the drug product.

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Valerie Jimenez, MS, Regulatory Project Manager, at (301) 796-1345.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

Hasmukh Patel

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