DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-804

WRITTEN REQUEST – AMENDMENT 2

Bausch & Lomb, Inc.
Attention: Mary Harrell
Senior Regulatory Affairs Specialist
Global Regulatory Affairs
8500 Hidden River Parkway
Tampa, FL 33637

Dear Ms. Harrell:

Please refer to your correspondence dated July 22, 2009, requesting changes to FDA's May 14, 2007, for Written Request for pediatric studies for Loteprednol Etabonate.

We have reviewed your proposed changes and are amending the Written Request to revise the time frame for submitting reports for the requested study to March 31, 2012. All other aspects of the May 14, 2007, Written Request remain unchanged.

If you have any questions, call Raphael R. Rodriguez, Regulatory Project Manager, at (301) 796-0798.

Sincerely,

{See appended electronic signature page}

Edward M. Cox, M.D., M.P.H.
Director
Office of Antimicrobial Product
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50804	GI-1	BAUSCH AND LOMB INC	ZYLET (LOTEPREDNOL ETABONATE/TOBRAMYCIN)

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/s/

RAPHAEL R RODRIGUEZ
10/15/2009

EDWARD M COX
12/16/2009