Medical Officer's Review of NDA 50-804
Phase 4 Commitment

NDA 50-804	**Submission Date:** June 25, 2009 **Received Date:** June 26, 2009 **Review Date:** July 20, 2009
Applicant:	Bausch & Lomb 8500 Hidden River Parkway Tampa, FL 33637 Contact: Julie Townsend (813) 866-2299
Drug:	Zylet (loteprednol etabonate /tobramycin ophthalmic suspension) 0.5%/0.3%
Pharmacologic Category:	Corticosteroid/anti-infective fixed combination
Dosage Form and Route of Administration:	Topical ocular ophthalmic suspension

Submitted:

Submitted is the final study report for Study #459, entitled, **"A Safety and Efficacy of Zylet (loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension) Compared to Vehicle in the Management of Lid Inflammation I Pediatric Subjects"** This final study report is intended to satisfy the Phase 4 commitment cited in the December 14, 2004, approval letter.

The Phase 4 commitment in that letter reads:

> Deferred pediatric study under PREA for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists in 60 pediatric patients ages 0 to 6 years.
>
> Final Study report Submission: March 31, 2007.

Study #459 is a multi-center, randomized, double-masked, vehicle-controlled study designed to evaluate the safety and efficacy of Zylet in pediatric subjects age zero to six years with lid inflammation (e.g. chalazion/hordeolum). A total of 108 subjects enrolled in the study. Seventy-six (76) subjects were randomized to Zylet and 36 subjects to

vehicle. Four (4) subjects enrolled in the Zylet treatment arm were between the ages 0-1 year.

There was no statistically significant difference between treatment groups in the efficacy and safety endpoints.

Reviewer's Comments:

The submitted final study report is adequate to satisfy the Phase 4 commitment as stated in the December 14, 2004, approval letter.

Conclusions/Recommended Regulatory Action:

The submitted final study report is adequate to satisfy the Phase 4 commitment as stated in the December 14, 2004, approval letter. The labeling should include the results of the study.

Lucious Lim, M.D., M.P.H.
Medical Officer

cc: NDA 50-804
HFD-520/Div/Files
HFD-520/CSO/Rodriguez
HFD-520/MO/Lim
HFD-520/CTL/Boyd
HFD-520/Acting Div Director/Chambers

Linked Applications	Submission Type/Number	Sponsor Name	Drug Name / Subject
NDA 50804	PMR/PMC 1		ZYLET (LOTEPREDNOL ETABONATE/TOBRAMYCIN)

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/s/

LUCIOUS LIM
08/18/2009

WILLIAM M BOYD
08/18/2009