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.


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

NDA 50-804 Zylet (loteprednol etabonate/tobramycin ophthalmic suspension) 0.5%/0.3%
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/s/

LUCIOUS LIM
08/18/2009

WILLIAM M BOYD
08/18/2009