Clinical Review of NDA 50-804
Supplemental New Drug Application - Labeling

NDA 50-804/S-015
SDN-86

Submission Date: March 11, 2010
Receipt Date: March 12, 2010
Review Date: March 24, 2010

Tradename: Zylet

Established Name: loteprednol etabonate 0.5% and tobramycin 0.3% ophthalmic suspension

Applicant: Bausch & Lomb
8500 Hidden River Parkway
Tampa, FL 33637
(813) 866-2299
Contact: Julie Townsend

Pharmacologic Category: Corticosteroid/anti-infective combination

Dosage Form and Route of Administration: Topical ocular ophthalmic suspension

Submitted:

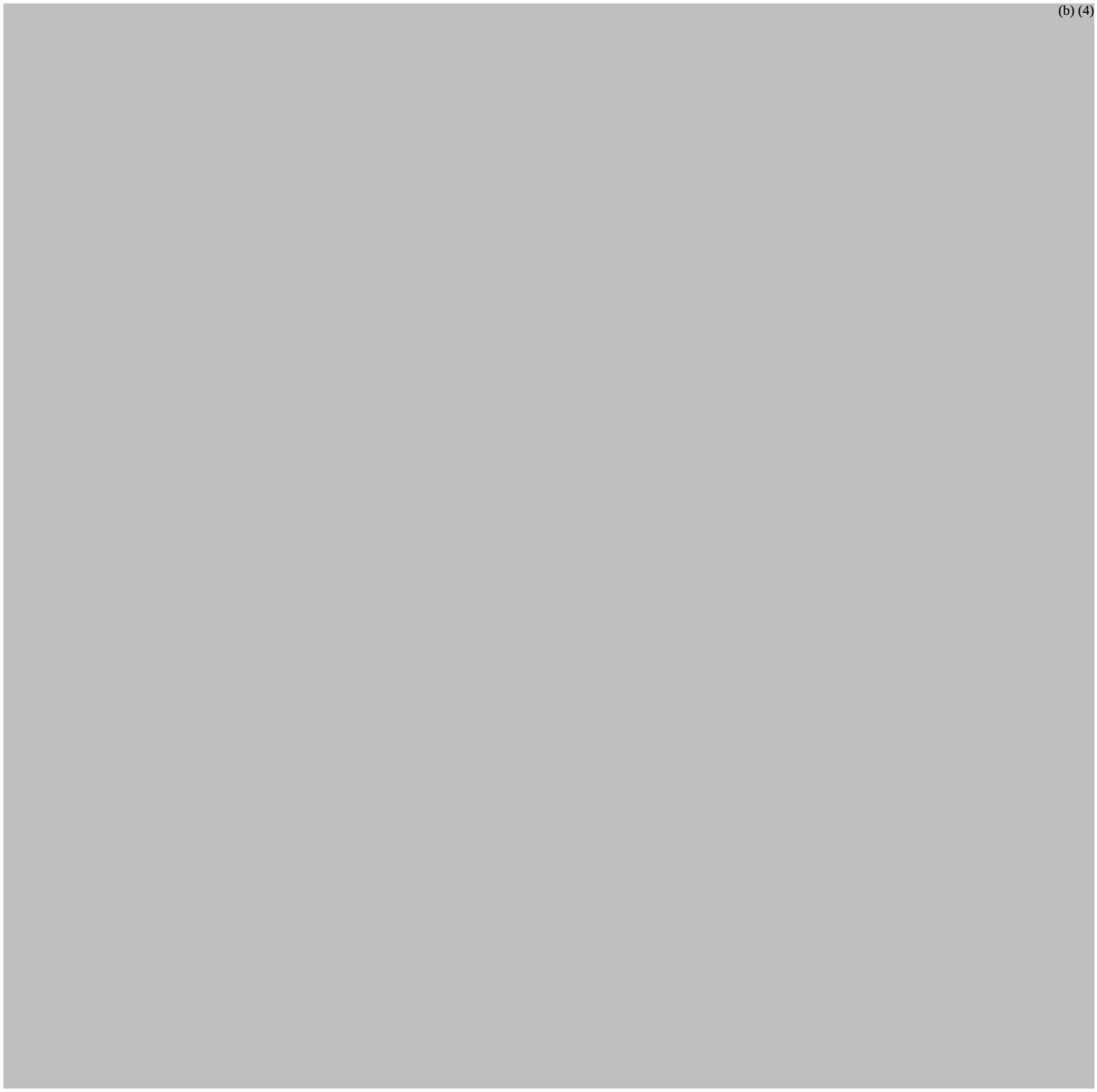
Submitted is a prior approval supplement for a revised package insert which includes an updated Pediatric Use section. Reference is made to a General Submission of the final study report for B&L Study #459 dated 25 June 2009 and a follow-up teleconference between the Division and Bausch & Lomb staff on 6 November 2009. This supplement revises the Pediatric Use section as agreed upon during the teleconference.

Proposed Package Insert

Following is the submitted package insert, presented for the first time in PLR format.

Applicant additions are shown by underline. Applicant deletions are shown by .

4 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

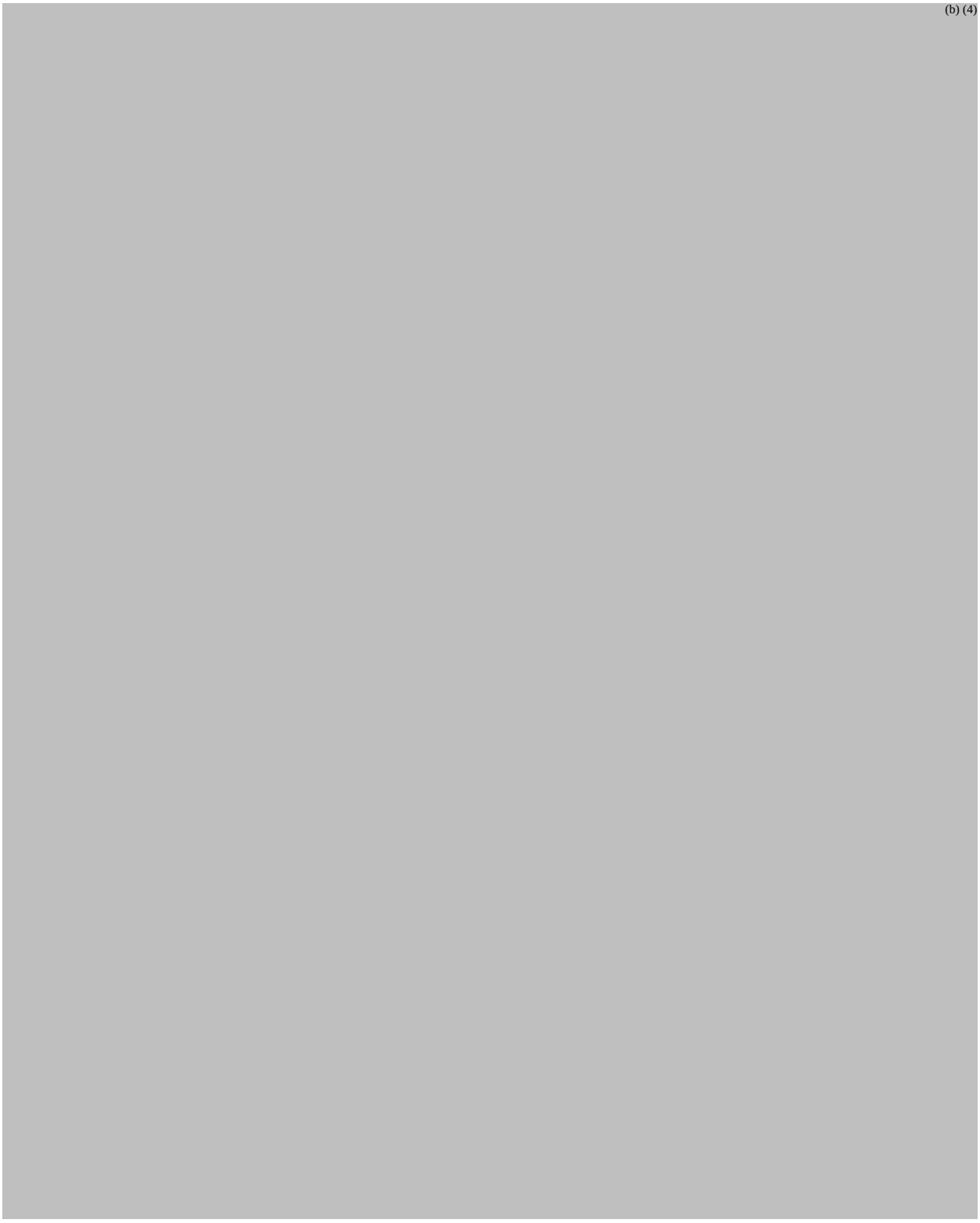


Pediatric Use: In a trial to evaluate the safety and efficacy of Zylet in pediatric patients age zero to six years with lid inflammation, Zylet with warm compresses did not demonstrate efficacy compared to vehicle with warm compresses. Patients received warm compress lid treatment plus Zylet or vehicle for 14 days. The majority of patients in both treatment groups showed reduced lid inflammation. There were no differences in safety assessments between treatment groups.

Reviewer's Comments:

The agreed-upon trial language has bean inserted into the Pediatric Section of the labeling. Acceptable.

(b) (4)



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Recommendations:

This supplement (NDA 50-804/S-015) is recommended for approval.

The Phase 4 commitment cited in the December 14, 2004, approval letter has been fully satisfied with the addition of trial information in the package insert (see M.O. review of SDN# 79 dated 8/18/09). A fulfillment letter can now be drafted.

William Boyd, M.D.
Clinical Team Leader

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50804	SUPPL-15	BAUSCH AND LOMB INC	ZYLET (LOTEPREDNOL ETABONATE/TOBRAMYCIN)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

WILLIAM M BOYD
04/28/2010

WILEY A CHAMBERS
05/04/2010