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APPLICATION NUMBER:

22-369

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

OFFICE OF CLINICAL PHARMACOLOGY REVIEW

NDA	22-369
Submission Date	June 26, 2008
Brand Name	TBD
Generic Name	Bimatoprost ophthalmic solution, 0.03%
Primary Reviewer	Sarah Robertson, Pharm.D.
Team Leader	Charles R. Bonapace, Pharm.D.
OCP Division	DCP4
OND Division	DAIOP
Applicant	Allergan
Relevant IND(s) / NDA(s)	IND 48,929, NDA 21,275
Submission Type; Code	Original NDA
Formulation; Strength	0.03% ophthalmic solution
Indication(s)	To improve the prominence of natural eyelashes as measured by increases in growth (length), fullness (thickness) and darkness (intensity)

EXECUTIVE SUMMARY

Bimatoprost is a synthetic prostamide approved for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. LUMIGAN® (bimatoprost ophthalmic solution, 0.03%) was approved in March 2001 (NDA 21-275). The current NDA seeks approval of bimatoprost ophthalmic solution, 0.03% to improve the prominence of natural eyelashes as measured by increases in growth (length), fullness (thickness) and darkness (intensity). The drug product is identical to that approved under NDA 21-275; only the color of the bottle cap has changed. The dose and dosing frequency are also unchanged (1 drop/eye once daily at bedtime). Unlike LUMIGAN®, in which a drop of solution is instilled directly into the eye, for the proposed indication a drop of the solution will be placed on a disposable applicator and applied to the upper eyelid margin at the base of the eyelashes.

In support of the NDA, the Sponsor submitted the results of a Phase 3 safety and efficacy study. No new clinical pharmacology data are submitted by the Sponsor. As the drug product, dose and dosing frequency are unchanged, the Sponsor is granted a waiver of the requirement to provide evidence of in vivo bioavailability based on 21 CFR 320.22(b)(1). Given the dose and route of administration (application to the upper eyelid), systemic exposure of bimatoprost is expected to be clinically negligible.

RECOMMENDATION

The NDA is acceptable from a clinical pharmacology perspective.

There are no recommended changes to the Sponsor's proposed label.

PHASE IV COMMITMENTS

No Phase IV commitments are recommended.

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/s/

Sarah M. Robertson
11/3/2008 09:25:21 AM
BIOPHARMACEUTICS

Charles Bonapace
11/5/2008 08:34:34 AM
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