Food and Drug Administration
Center for Drug Evaluation and Research

Summary Minutes of the Dermatologic and Ophthalmic Drugs Advisory Committee Meeting
December 5, 2008

Topic: The committee discussed new drug application (NDA) 22-308, besifloxacin ophthalmic suspension, Bausch & Lomb, Inc., proposed for the treatment of bacterial conjunctivitis and NDA 22-369, bimatoprost ophthalmic solution, 0.03%, Allergan, Inc., proposed for the treatment of hypotrichosis of the eyelids.

These summary minutes for the December 5, 2008 Dermatologic and Ophthalmic Drugs Advisory Committee meeting were approved on December 16, 2008.

I certify that I attended the December 5, 2008 Dermatologic and Ophthalmic Drugs Advisory Committee meeting and that these minutes accurately reflect what transpired.

_____-*s*-_____
Yvette Waples, Pharm.D.
(Designated Federal Official)

_____-*s*-_____
Michael X. Repka, M.D.
(Acting Chair)

Summary Minutes of the Dermatologic and Ophthalmic Drugs Advisory Committee Meeting
December 5, 2008

The following is the final report of the Dermatologic and Ophthalmic Drugs Advisory Committee meeting held on December 5, 2008. A verbatim transcript will be available in approximately six weeks, sent to the Division and posted on the FDA website at http://www.fda.gov/ohrms/dockets/ac/cder08.html#DermatologicOphthalmicDrugs

All external requests for the meeting transcripts should be submitted to the CDER Freedom of Information Office.

The Dermatologic and Ophthalmic Drugs Advisory Committee of the Food and Drug Administration met on December 5, 2008 at the Hilton Washington/Rockville 1750 Rockville Pike, Rockville, Maryland. Michael X. Repka, M.D., chaired the meeting. There were approximately 60 in attendance.

Attendance:

Dermatologic and Ophthalmic Drugs Advisory Committee Members present (voting):
Mary A. Majumder, J.D., Ph.D.

Dermatologic and Ophthalmic Drugs Advisory Committee Members absent:
Bruce H. Thiers, M.D.

Temporary Voting Members:
Natalie Afshari, M.D., FACS ; Warren B. Bilker, Ph.D.; William G. Gates, M.D.; Philip Lavin, Ph.D.; Marijean M. Miller, M.D.; Michael X. Repka, M.D.; M. Roy Wilson, M.D., M.S.; Paula Cofer (Patient Representative)

Industry Representative (non-voting):
Ellen Strahlman, M.D., M.H.Sc

FDA Participants (non-voting):
Edward M. Cox, M.D., MPH; Wiley Chambers, M.D.; Martin Nevitt, M.D., M.P.H.; Rhea Lloyd, M.D.

Open Public Hearing Speaker:
Brandel France deBravo (National Research Center for Women and Families)

On December 5, 2008, the committee met to discuss new drug application (NDA) 22-308, besifloxacin ophthalmic suspension, Bausch & Lomb, Inc., proposed for the treatment of bacterial conjunctivitis and NDA 22-369, bimatoprost ophthalmic solution, 0.03%, Allergan, Inc., proposed for the treatment of hypotrichosis of the eyelids.

Michael X. Repka, M.D. (Acting Chair) called the meeting to order at 8:00 a.m. The Committee members and the FDA participants introduced themselves. The conflict of interest statements were read into the record by Yvette Waples, Pharm.D., Designated Federal Official (DFO). The agenda for the meeting was as follows:

Session 1: The committee met to discuss new drug application (NDA) 22-308, besifloxacin ophthalmic suspension, Bausch & Lomb, Inc., proposed for the treatment of bacterial conjunctivitis.

Call to Order and Opening Remarks	**Michael X. Repka, M.D.** Acting Chair, Dermatologic and Ophthalmic Drugs Advisory Committee
Introduction of Committee	
Conflict of Interest Statement	**Yvette W. Waples, Pharm.D.** Designated Federal Official
FDA Introductory Remarks	**Wiley Chambers, M.D.** Acting Director, Division of Anti-Infective and Ophthalmic Products, CDER, FDA

INDUSTRY PRESENTATION

Introduction and Presentation	**John F. Weet, Ph.D.** Vice President, Global Regulatory Affairs, Pharmaceuticals Bausch & Lomb Incorporated
Disease Background	**Susan Schneider, M.D.** Director of Global Clinical Development Clinical & Scientific Affairs, Pharmaceuticals Bausch & Lomb Incorporated
Nonclinical Microbiology	**Timothy W. Morris, Ph.D.** Senior Principal Scientist Bausch & Lomb Incorporated
Efficacy	**Timothy L. Comstock, O.D., M.S.** Director, Pharmaceutical Medical Affairs Bausch & Lomb Incorporated
Safety and Conclusions	**Susan Schneider, M.D.** Director of Global Clinical Development Clinical & Scientific Affairs, Pharmaceuticals

	Bausch & Lomb Incorporated
Questions/Clarifications	
BREAK	

FDA PRESENTATION

Division of Anti-Infective and Ophthalmology Products: Advisory Committee Meeting for Besifloxacin Hydrochloride Ophthalmic Suspension for the Treatment of Bacterial Conjunctivitis	**Martin Nevitt, M.D., M.P.H.** Medical Officer, Division of Anti-Infective and Ophthalmic Products, CDER, FDA
Questions/Clarifications	
BREAK	
OPEN PUBLIC HEARING	
Panel Discussion/Questions	
LUNCH BREAK	

Session 2: The committee will discuss new drug application (NDA) 22-369, bimatoprost ophthalmic solution, 0.03%, Allergan, Inc., proposed for the treatment of hypotrichosis of the eyelids.

Afternoon Opening Remarks	**Michael X. Repka, M.D.** Acting Chair, Dermatologic and Ophthalmic Drugs Advisory Committee
Conflict of Interest Statement	**Yvette W. Waples, Pharm.D.** Designated Federal Official
FDA Introductory Remarks	**Wiley Chambers, M.D.** Acting Director, Division of Anti-Infective and Ophthalmic Products, CDER, FDA

INDUSTRY PRESENTATION

Introduction and Overview	**Scott Whitcup, M.D.** Head, Research & Development Allergan, Incorporated
Clinical Overview	**Frederick Beddingfield, M.D.** Therapeutic Area Head, Dermatology Clinical Research

	Allergan, Incorporated
Safety Overview	**Sef Kurstjens, M.D.** Chief Medical Officer and Head, Global Drug Development Allergan, Incorporated
Questions/Clarifications	
BREAK	

FDA PRESENTATION

Division of Anti-Infective and Ophthalmology Products: Advisory Committee Meeting for Bimatoprost Ophthalmic Solution for the Treatment of Hypotrichosis of the Eyelashes	**Rhea Lloyd, M.D.** Medical Officer, Division of Anti-Infective and Ophthalmic Products, CDER, FDA
Questions/Clarifications	
BREAK	
OPEN PUBLIC HEARING	
Panel Discussion/Questions	
ADJOURNMENT	

Questions to the Committee:

NDA 22-308 Besifloxacin Ophthalmic Suspension

1. Do you think besifloxacin hydrochloride ophthalmic suspension should be approved for the treatment of bacterial conjunctivitis?

Committee Discussion:
Yes: 9 No: 0 Abstain: 0
(See Transcript for Complete Discussion)

The committee agreed that safety and efficacy was demonstrated by the data presented.

2. If not, what additional studies should be performed?

Committee Discussion:

No discussion or comments

3. Do you have any suggestions concerning the labeling of the product?

   Committee Discussion:
   The committee made suggestions to add language for use in patients with pre-existing dry eye and other corneal surface conditions. The committee also suggested referring to moxifloxacin labeling for guidance.
   (See Transcript for Complete Discussion)

NDA 22-369 Bimatoprost Ophthalmic Solution, 0.03%,

1. Do you think the benefits outweigh the risks for Latisse (bimatoprost ophthalmic solution) 0.03% for the treatment of hypotrichosis of the eyelashes?

   Committee Discussion:
   Yes: 9 No: 0 Abstain: 0
   (See Transcript for Complete Discussion)

   The committee agreed that safety and efficacy was demonstrated by the data presented.

2. If not, what additional studies should be performed?

   Committee Discussion:
   No discussion or comments

3. If yes, should any additional Phase 4 studies be performed?
   Committee Discussion:
   Yes: 5 No: 3 Abstain: 1
   (See Transcript for Complete Discussion)

   The committee was divided on this issue.

   For those not in favor of performing Phase 4 studies viewed that there is sufficient data with Lumigan® to not perform any Phase 4 studies with bimatoprost 0.03%. Suggestions were made to perform risk management programs or establish a tracking program in lieu of performing Phase 4 studies.

For those in favor of performing Phase 4 studies made the following recommendations:

- **pediatric and adolescent studies**
- **studies including patients with autoimmune disease or on chemotherapy**
- **studies including patients of various ethnicities**
- **lower lash studies**

(See Transcript for Complete Discussion)

4. Do you have any suggestions concerning the labeling of the product?

Committee Discussion:
The committee recommended the labeling include the following:

- **Continued use is necessary**
- **Wording of ocular pigmentation in layman terms**
- **Information on side effects and drug interactions**
- **What conditions should you call an ophthalmologist**
- **Language to include Lumigan® has been tested in children although this product to date has not been tested**

(See Transcript for Complete Discussion)

The meeting was adjourned at approximately 3:00 p.m. on December 5, 2008.