

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Dermatologic and Ophthalmic Drugs Advisory Committee Meeting***

HILTON WASHINGTON DC /ROCKVILLE  
ROCKVILLE, MARYLAND

DECEMBER 5, 2008

**AGENDA**

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

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8:00 a.m. 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

8:15 a.m. FDA Introductory Remarks

**Wiley Chambers, M.D.**  
Acting Director, Division of Anti-Infective and  
Ophthalmic Products, CDER, FDA

**INDUSTRY PRESENTATION**

8:20 a.m. 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

9:05 a.m. Questions/Clarifications

9:20 a.m. **BREAK**

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**-CONTINUED-**

**FDA PRESENTATION**

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|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| 9:35 a.m.   | Division of Anti-Infective and Ophthalmology Products: Advisory Committee Meeting for Besifloxacin Hydrochloride Ophthalmic Suspension for the Treatment of Bacterial Conjunctivitis | <b>Martin Nevitt, M.D., M.P.H.</b><br>Medical Officer, Division of Anti-Infective and Ophthalmic Products, CDER, FDA |
| 10:05 a.m.  | Questions/Clarifications                                                                                                                                                             |                                                                                                                      |
| 10:20 a.m.  | <b>BREAK</b>                                                                                                                                                                         |                                                                                                                      |
| 10: 40 a.m. | <b>OPEN PUBLIC HEARING</b>                                                                                                                                                           |                                                                                                                      |
| 11: 10 a.m. | Panel Discussion/Questions                                                                                                                                                           |                                                                                                                      |
| 12:10 p.m.  | <b>BREAK</b>                                                                                                                                                                         |                                                                                                                      |

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**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.

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1:00 p.m. 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

1:10 p.m. FDA Introductory Remarks **Wiley Chambers, M.D.**  
Acting Director, Division of Anti-Infective and  
Ophthalmic Products, CDER, FDA

**INDUSTRY PRESENTATION**

1:15 a.m. 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

2:00 p.m. Questions/Clarifications

2: 15 p.m. **BREAK**

**FDA PRESENTATION**

2:30 p.m. Division of Anti-Infective and **Rhea Lloyd, M.D.**  
Ophthalmology Products: Advisory  
Committee Meeting for Bimatoprost  
Ophthalmic Solution for the Treatment  
of Hypotrichosis of the Eyelashes  
Medical Officer, Division of Anti-Infective and  
Ophthalmic Products, CDER, FDA

3:00 p.m. Questions/Clarifications

3:15 p.m. **BREAK**

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- 3: 30 p.m.    **OPEN PUBLIC HEARING**
- 4: 00 p.m.    Panel Discussion/Questions
- 5:00 p.m.    **ADJOURNMENT**

DRAFT