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

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.

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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FDA PRESENTATION

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	**Martin Nevitt, M.D., M.P.H.** Medical Officer, Division of Anti-Infective and Ophthalmic Products, CDER, FDA
10:05 a.m.	Questions/Clarifications	
10:20 a.m.	**BREAK**	
10: 40 a.m.	**OPEN PUBLIC HEARING**	
11: 10 a.m.	Panel Discussion/Questions	
12:10 p.m.	**BREAK**	

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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.

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
:00 p.m.	Questions/Clarifications	
2: 15 p.m.	**BREAK**	
FDA PRESENTATION		
2:30 p.m.	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
3:00 p.m.	Questions/Clarifications	
3:15 p.m.	**BREAK**	
3: 30 p.m.	**OPEN PUBLIC HEARING**	
4: 00 p.m.	Panel Discussion/Questions	
5:00 p.m.	**ADJOURNMENT**	