

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
Dermatologic and Ophthalmic Drugs Advisory Committee
Marriott Inn and Conference Center
University of Maryland University College (UMUC)
Adelphi, Maryland
June 17, 2011

AGENDA

The committee will discuss biologic license application (BLA) 125387, aflibercept ophthalmic solution, proposed trade name EYLEA, sponsored by Regeneron Pharmaceuticals, Inc., indicated for the treatment of neovascular age-related macular degeneration (wet AMD).

8:00 a.m. – 8:05 a.m.	Call to Order and Introductions	Michael Repka, M.D. <i>Committee Chair</i> Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC)
8:05 a.m. – 8:15 a.m.	Conflict of Interest Statement	Yvette Waples, Pharm.D. Designated Federal Officer DODAC
8:15 a.m. – 8:20 a.m.	FDA Introductory Remarks	Wiley Chambers, M.D. Deputy Director Division of Transplant and Ophthalmology Products (DTOP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND) Center for Drug Evaluation & Research (CDER) Food and Drug Administration (FDA)
8:20 a.m. – 9:50 a.m.	Sponsor Presentation	Regeneron Pharmaceuticals, Inc.
	Introduction	George Yancopoulos, M.D., Ph.D. Chief Scientific Officer Regeneron Pharmaceuticals, Inc.
	Medical Need	Jeffrey Heier, M.D. Vitreoretinal Specialist, Ophthalmic Consultants of Boston Assistant Professor of Ophthalmology, Tufts University School of Medicine Clinical Instructor of Ophthalmology, Harvard Medical School
	Clinical Pharmacology	Neil Stahl, Ph.D. Sr. Vice President Research and Development Sciences Regeneron Pharmaceuticals, Inc.

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AGENDA (cont.)

Efficacy	Robert Vitti, M.D., M.B.A. Vice President Clinical Sciences, Ophthalmology Regeneron Pharmaceuticals, Inc.
Safety	Ned Braunstein, M.D. Executive Director Regulatory Affairs Regeneron Pharmaceuticals, Inc.
Benefit-Risk	Peter Kaiser, M.D. Professor of Ophthalmology, Cleveland Clinic Lerner College of Medicine Vitreoretinal Surgeon Cole Eye Institute, Cleveland Clinic Founding Director, Digital Coherence Tomography Reading Center, Cole Eye Institute
9:50 a.m. – 10:05 a.m.	Clarifying Questions from the Committee to Sponsor
10:05 a.m. – 10:20 a.m.	Break
10:20 a.m. – 11:30 a.m.	FDA Presentation
	Aflibercept BLA 125387
	Sonal Wadhwa, M.D. Clinical Reviewer DTOP, OAP, OND, CDER, FDA
11:30 a.m. – 11:45 p.m.	Clarifying Questions from the Committee to FDA
11:45 p.m. – 12:45 p.m.	Lunch
12:45 p.m. – 1:45 p.m.	Open Public Hearing Session
1:45 p.m. – 3:00 p.m.	Discussion/Questions to the Committee
3:00 p.m. – 3:15 p.m.	Break
3:15 p.m. – 4:30 p.m.	Questions to the Committee (<i>cont'd</i>)
4:30 p.m.	Adjournment