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

Joint Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) and the Ophthalmic Devices Panel of the Medical Devices Advisory Committee (OP-MDAC)
FDA White Oak Campus, Building 31, the Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
February 24, 2015

AGENDA

The committees will discuss new drug application (NDA) 203324, for riboflavin ophthalmic solutions with UV-A Irradiation, submitted by Avedro, Inc. The combination products are used in corneal collagen cross-linking and proposed to be indicated for the treatment of progressive keratoconus or corneal ectasia following refractive surgery.

8:00 a.m.	Call to Order and Introduction of Committee	**Richard Awdeh, MD** Acting Chairperson, DODAC
8:10 a.m.	Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Acting Designated Federal Officer, DODAC
8:15 a.m.	FDA Introductory Remarks	**Wiley A. Chambers, MD** Deputy Director Division of Transplant and Ophthalmology Products (DTOP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**SPONSOR PRESENTATIONS**	**Avedro, Inc.**
	Introduction	**David Muller, PhD** President and Chief Executive Officer Avedro, Inc.
	Disease Background and unmet Medical Need in the U.S.	**Rajesh Rajpal, MD** Founder See Clearly Vision Group
	Phase 3 Clinical Study Design	**Peter Hersh, MD, FACS** Medical Monitor, Avedro, Inc. Director, Cornea & Laser Eye Institute – Hersh Vision Group Clinical Professor of Ophthalmology, Rutgers Medical School Visiting Researcher, Princeton University
	Efficacy and Safety of Corneal Collagen Cross-linking	**Peter Hersh, MD, FACS**
9:35 a.m.	Clarifying Questions	
10:05 a.m.	**BREAK**	

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AGENDA (cont.)

10:20 a.m.	**FDA PRESENTATIONS**	
	Clinical Overview	**William Boyd, MD** Clinical Team Leader, Ophthalmology Division of Transplant and Ophthalmology Products Center for Drug Evaluation and Research
10:25 a.m.	Device Constituent Presentation	**Maryam Mokhtarzadeh, MD** Medical Officer Division of Ophthalmic and Ear, Nose and Throat Devices Office of Device Evaluation Center for Devices and Radiological Health
10:35 a.m.	Clinical Overview (cont.)	**William Boyd, MD**
10:40 a.m.	Efficacy Results	**Dongliang Zhuang, PhD** Statistical Reviewer Division of Biometrics IV Office of Biostatistics/Office of Translational Sciences Center for Drug Evaluation and Research
11:00 a.m.	Safety Review and Summary	**William Boyd, MD**
11:20 a.m.	Device Perspective Summary	**Maryam Mokhtarzadeh, MD** Medical Officer Division of Ophthalmic and Ear, Nose and Throat Devices Office of Device Evaluation Center for Devices and Radiological Health
11:35 a.m.	Clarifying Questions	
12:05 p.m.	**LUNCH**	
1:05 p.m.	Open Public Hearing	
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:15 p.m.	**BREAK**	
3:30 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	