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

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting
January 9, 2023

DRAFT AGENDA

The committee will discuss supplemental biologics license application (sBLA) 125387, aflibercept solution for intravitreal injection, submitted by Regeneron Pharmaceuticals, Inc. The supplement was submitted in response to FDA's pediatric written request. FDA's written request was for studies of aflibercept in the treatment of retinopathy of prematurity.

9:30 a.m.	Call to Order	**James Chodosh, MD** Chairperson, DODAC
9:35 a.m.	Introduction of Committee and Conflict of Interest Statement	**LaToya Bonner, PharmD** Designated Federal Officer, DODAC
9:40 a.m.	FDA Introductory Remarks	**Wiley Chambers, MD** Director Division of Ophthalmology (DO) Office of New Drugs (OND), CDER, FDA
9:45 a.m.	**APPLICANT PRESENTATIONS**	**Regeneron Pharmaceuticals, Inc.**
	Introduction	**Boaz Hirshberg MD, MBA** Senior Vice President (VP) Clinical Sciences General Medicine Regeneron
	Disease Background and Unmet Need	**Faruk Orge, MD** Professor of Ophthalmology and Pediatrics Director of Pediatric Ophthalmology and Adult Strabismus Case Western Reserve University and Rainbow Babies and Children's Hospital
	Efficacy	**Robert Vitti, MD, MBA** VP, Clinical Sciences Ophthalmology Regeneron
	Safety	**Suzanne Green, MBChB, FPM** Therapy Area Head Global Patient Safety Regeneron

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DRAFT AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Perspective	**Steven Donn, MD, FAAP, FAARC** Professor Emeritus of Pediatrics Division of Neonatal-Perinatal Medicine University of Michigan Medical School and C.S. Mott Children's Hospital
10:45 a.m.	Clarifying Questions to Applicant	
11:15 a.m.	**FDA PRESENTATIONS**	
	EYLEA (aflibercept) Treatment of Retinopathy of Prematurity	**Wiley Chambers, MD**
12:15 p.m.	Clarifying Questions to FDA	
12:45 p.m.	**LUNCH**	
1:45 p.m.	**OPEN PUBLIC HEARING**	
3:15 p.m.	**BREAK**	
3:30 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	