

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

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

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 Office of Specialty Medicine Office of New Drugs, CDER, FDA
9:45 a.m.	APPLICANT PRESENTATIONS	Regeneron Pharmaceuticals, Inc.
	EYLEA® (aflibercept) for the Treatment of Retinopathy of Prematurity Introduction	Boaz Hirshberg MD, MBA Senior Vice President (VP) Clinical Sciences General Medicine Regeneron Pharmaceuticals, Inc.
	Disease Background and Unmet Need	Faruk Öрге, MD Professor of Ophthalmology and Pediatrics Case Western Reserve University Director of Pediatric Ophthalmology and Adult Strabismus Rainbow Babies and Children's Hospital
	Efficacy	Robert Vitti, MD, MBA VP, Clinical Sciences Ophthalmology Regeneron Pharmaceuticals, Inc.
	Safety	Suzanne Green, MBChB Therapy Area Head, Global Patient Safety Regeneron Pharmaceuticals, Inc.

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Clinical Perspective

Steven Donn, MD, FAAP, FAARC
Professor Emeritus of Pediatrics
Division of Neonatal-Perinatal Medicine
C.S. Mott Children's Hospital
University of Michigan Medical School

10:45 a.m. Clarifying Questions to Applicant

11:15 a.m. **FDA PRESENTATIONS**

EYLEA (afibercept)
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**