FOOD AND DRUG ADMINISTRATION (FDA)
Office of the Commissioner (OC)

Pediatric Advisory Committee (PAC)
September 15, 2020

AGENDA

The committee will discuss the pediatric-focused safety reviews for Vyvanse (lisdexamfetamine); Adzenys ER (amphetamine) extended-release oral suspension; Mydayis (mixed salts of a single-entity amphetamine product) extended-release capsule, for oral use; Orencia (abatacept); FLOURISH Pediatric Esophageal Atresia Device (humanitarian device exemption); GAMUNEX®-C (immune globulin intravenous [human]), 10% Caprylate/Chromatography Purified as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107-109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108-155).

10:00 a.m.	Call to Order and Introduction of Committee	**Kelly Wade, MD** Chairperson, PAC
	Conflict of Interest Statement	**Marieann Brill, MBA, RAC, MT(ASCP)** Designated Federal Officer, PAC Office of Pediatric Therapeutics (OPT) Office of Clinical Policy and Programs (OCPP) Office of the Commissioner (OC), FDA
.	FDA Opening Remarks	**Susan McCune, MD** Director OPT, OCPP, OC, FDA
10:30 a.m.	Center for Drug Evaluation and Research (CDER): Standard Review of Adverse Event Presentation • Vyvanse (lisdexamfetamine dimesylate)	**Ivone Kim, MD, FAAP** Medical Officer Division of Pharmacovigilance I Office of Surveillance and Epidemiology (OSE) CDER, FDA
	• Mydayis (mixed salts of a single-entity amphetamine product) and Adzenys ER (amphetamine)	**Mohamed Mohamoud, PharmD, MPH, BCPS** Safety Evaluator Division of Pharmacovigilance I Office of Surveillance and Epidemiology (OSE) CDER, FDA
11:30 a.m.	**OPEN PUBLIC HEARING**	
12:30 p.m.	**LUNCH**	
1:00 p.m.	Committee Discussion and Vote	
1:45 p.m.	CDER: Standard Review of Adverse Event Presentation cont'd	

	• Orencia (abatacept) • *Committee Discussion and Vote*	**Lisa Harinstein, Pharm D, BCCCP** Team Lead Division of Pharmacovigilance I Office of Surveillance and Epidemiology (OSE) CDER, FDA
2:15 p.m.	Center for Biologics Evaluation and Research (CBER) Standard Review of Adverse Event Presentation • Gamunex-C (immune globulin intravenous [human]), 10%, Caprylate/Chromatography Purified • *Committee Discussion and Vote*	**Craig Zinderman, MD, MPH** Associate Director for Medical Policy Office of Biostatistics and Epidemiology CBER, FDA
2:45 p.m.	**BREAK**	
3:00 p.m ..	FDA Presentation Center for Devices and Radiological Health (CDRH) Annual Update of Post-Market Humanitarian Device Exemption (HDE) Review • FLOURISH Pediatric Esophageal Atresia Device (HDE)	**Priya Venkataraman-Rao, M.D., FAAP** Senior Clinical Advisor, Outreach & Partnerships Team 2 *Medical Product Safety Network (MedSun)* DCEA1: Division of Clinical Science and Quality I Office of Clinical Evidence and Analysis Office of Product Evaluation and Quality CDRH/FDA
3:30 p.m.	Sponsor Presentation Flourish™ Pediatric Esophageal Atresia Device	**Ted Heise, PhD, RAC** VP Regulatory & Clinical Services MED Institute, Inc. **Mario Zaritzky, MD** Radiologist University of Chicago Medicine Comer Children's Hospital **Bethany Slater, MD, MBA** University of Chicago Medicine, Comer Children's Hospital

AGENDA (cont.)

4:00 p.m. *Committee Discussion and Vote*

4:30 p.m. **ADJOURNMENT** **Kelly Wade, MD,**
Chairperson, PAC