

FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

Pediatric Advisory Committee (PAC)

September 15, 2020

FINAL MEETING 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).

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| 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 <ul style="list-style-type: none">• Vyvanse (lisdexamfetamine dimesylate) | Ivone Kim, MD, FAAP
Medical Officer
Division of Pharmacovigilance I
Office of Surveillance and Epidemiology (OSE)
CDER, FDA |
| | <ul style="list-style-type: none">• 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 | |
| 11:40 a.m. | Clarifying Questions | |
| 12:30 p.m. | LUNCH | |
| 1:00 p.m. | Committee Discussion and Vote | |

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2:41 p.m.	CDER: Standard Review of Adverse Event Presentation cont'd <ul style="list-style-type: none">• Orenzia (abatacept)• <i>Committee Discussion and Vote</i>	Lisa Harinstein, Pharm D, BCCCP Team Lead Division of Pharmacovigilance I Office of Surveillance and Epidemiology (OSE) CDER, FDA
3:33 p.m.	Center for Biologics Evaluation and Research (CBER) Standard Review of Adverse Event Presentation <ul style="list-style-type: none">• Gamunex-C (immune globulin intravenous [human]), 10%, Caprylate/Chromatography Purified• <i>Committee Discussion and Vote</i>	Craig Zinderman, MD, MPH Associate Director for Medical Policy Office of Biostatistics and Epidemiology CBER, FDA
4:14 p.m.	FDA Presentation Center for Devices and Radiological Health (CDRH) Annual Update of Post-Market Humanitarian Device Exemption (HDE) Review <ul style="list-style-type: none">• FLOURISH Pediatric Esophageal Atresia Device (HDE)	Priya Venkataraman-Rao, M.D., FAAP Senior Clinical Advisor, Outreach & Partnerships Team 2 <i>Medical Product Safety Network (MedSun)</i> DCEA1: Division of Clinical Science and Quality I Office of Clinical Evidence and Analysis Office of Product Evaluation and Quality CDRH/FDA
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4:40 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

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FINAL MEETING AGENDA (cont.)

4:49 p.m. *Committee Discussion and Vote*

5:35 p.m. **ADJOURNMENT**

Kelly Wade, MD,
Chairperson, PAC