

FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

Pediatric Advisory Committee (PAC)

September 17, 2021

FINAL MEETING AGENDA

The committee will discuss the pediatric-focused safety reviews, 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). The PAC will meet to discuss FLOURISH Pediatric Esophageal Atresia Device (HDE).

- 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 **Dionna Green, MD**
Director (Acting)
OPT, OCPP, OC, FDA
- 10:30 a.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) **Lauren J. Min, PhD**
Epidemiologist
DHT3A: Division of Gastroenterology, Renal, Endoscopy, Transplant and Obesity Devices
OHT3: Office of Reproductive, Gastro-Renal, Urological, General Hospital Devices & Human Factors
Office of Product Evaluation and Quality (OPEQ)
CDRH, FDA
- Jian Connell, DNP, MSN, CPN**
Consumer Safety Officer/Senior MDR Analyst
DHT3A, OHT3, OPEQ, CDRH, FDA
- 11:00 a.m. Sponsor Presentation
- FLOURISH Pediatric Esophageal Atresia Device (HDE) **Ted Heise, PhD, RAC**
VP Regulatory & Clinical Services
MED Institute, Inc.
- Clarifying Questions*
- 11:30 a.m. **OPEN PUBLIC HEARING**

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FINAL MEETING AGENDA (cont.)

11:32 a.m. Clarifying Questions cont'd

12:30 p.m. **LUNCH**

1:00 p.m. *Committee Discussion and Vote*

3:00 p.m. **ADJOURNMENT**

Kelly Wade, MD
Chairperson, PAC