Dionna Green, MD, FCP
Acting Director, Office of Pediatric Therapeutics
Office of Clinical Policy and Programs
Office of the Commissioner, FDA

PEDIATRIC ADVISORY COMMITTEE OPENING REMARKS

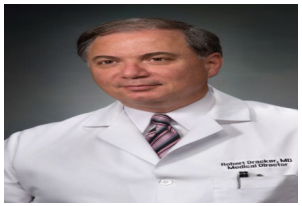
Pediatric Advisory Committee Meeting
September 17, 2021

Opening Remarks

- Personnel Update
- Web Posted Reviews
- Non-Compliance Letters
- Agenda

Personnel Update

- PAC
  - Robert Dracker, MD, MHA, MBA, CPI



  - Bridgette Jones, MD, MS

  - Angela Czaja, MD, MSc, PhD

- OPT
  - Susan McCune, MD

Web Posted Reviews

- **Center for Drug Evaluation and Research (N=12)**
  - APTIOM (eslicarbazepine acetate)
  - COTEMPLA (methylphenidate extended release orally disintegrating tablets)
  - CIALIS (tadalafil)
  - EMEND (fosaprepitant dimeglumine)
  - ENBREL (etanercept), Erelzi (etanercept-szzs), Eticovo (etanercept-ykro)
  - FASENRA (benralizumab)
  - INTELENCE (etravirine)
  - PEGASYS (peginterferon alpha-2a)
  - TEKTURNA (aliskiren hemifumarate)
  - VIMOVO (naproxen/esomeprazole magnesium)
  - VIREAD (tenofovir disoproxil fumarate)
  - XOFLUZA (baloxavir marboxil)

- **Center for Biologics Evaluation and Research (N=7)**
  - CUVITRU (Immune Globulin Subcutaneous (Human) (IGSC), 20% Solution)
  - EPICEL (cultured epidermal autografts)
  - JIVI (Antihemophilic Factor (Recombinant), PEGylated-aucl)
  - REBINYN (nonacog beta pegol (N9-GP))
  - ROTATEQ (Rotavirus Vaccine, Live, Oral, Pentavalent)
  - RUBBER PANEL T.R.U.E. TEST (Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test)
  - T.R.U.E. TEST (Thin-Layer Rapid Use Epicutaneous Patch Test)

- **Center for Devices and Radiological Health (N=9)**
  - CONTEGRA PULMONARY VALVED CONDUIT (Humanitarian Device Exemption (HDE))
  - ELANA SURGICAL KIT (HDE)
  - ENTERRA THERAPY SYSTEM (HDE)
  - LIPOSORBER® LA-15 SYSTEM (HDE)
  - MEDTRONIC ACTIVA® DYSTONIA THERAPY (HDE)
  - MINIMALLY INVASIVE DEFORMITY CORRECTION (MID-C) SYSTEM (HDE)
  - PLEXIMMUNE™ IN-VITRO DIAGNOSTIC TEST (HDE)
  - PULSERIDER ANEURYSM NECK RECONSTRUCTION DEVICE (HDE)
  - THE TETHER™ – VERTEBRAL BODY TETHERING SYSTEM (HDE)

https://www.fda.gov/advisory-committees/pediatric-advisory-committee/web-posted-pediatric-safety-reviews

PREA Non-Compliance Letters

- Center for Biologics Evaluation and Research (n=2)
  - https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm448393.htm
- Center for Drug Evaluation and Research (n=91)
  - https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm
- The websites list the sponsor, product, a copy of the non-compliance letter, the sponsor's response (if available), and the status of the PREA requirement (e.g., released, replaced, fulfilled)

Non-Compliance Letters

- Center for Biologics Evaluation and Research (n=2)
  - No new letters since the last PAC meeting

- Center for Drug Evaluation and Research (n=91)
  - 21 new letters since the last PAC meeting

Non-Compliance Letters (CDER)

Sponsor	Product	Date of Letter
Lannett Company, Inc.	Numbrino (cocaine hydrochloride) nasal solution	7/9/21
Currax Pharmaceuticals LLC	Treximet (sumatriptan and naproxen sodium) tablets	06/24/21
Sanofi-Aventis US LLC	Allegra-D 12 Hour Allergy & Congestion (fexofenadine hydrochloride 60 mg and pseudoephedrine 120 mg) extended-release tablet	6/21/21
Exela Pharma Sciences, LLC	Akovaz (ephedrine sulfate injection, USP)	6/16/21
Fresenius Kabi USA, LLC	Smoflipid (lipid injectable emulsion)	5/24/21
Belcher Pharmatech LLC	esomeprazole strontium capsule	5/5/21
USWM, LLC	Lucemyra (lofexidine hydrochloride) tablets	4/19/21
Tris Pharma, Inc.	QuilliChew ER (methylphenidate HCl) extended-release chewable tablets	4/17/21
Hospira, Inc.	Precedex (dexmedetomidine hydrochloride) Injection	4/1/21
Alexza Pharmaceuticals, Inc.	Adasuve (loxapine) inhalation powder for oral inhalation use	2/19/21

Non-Compliance Letters (CDER)

Sponsor	Product	Date of Letter
Azurity Pharmaceuticals, Inc.	Katerzia (amlodipine besylate USP; amlodipine benzoate) suspension	2/25/21
Azurity Pharmaceuticals, Inc.	Qbrelis (lisinopril) oral solution	1/21/21
Currax Pharmaceuticals, LLC	Onzetra Xsail (sumatriptan nasal powder) 11mg	8/12/20
Hikma Pharmaceuticals USA, Inc.	Codeine sulfate tablet and oral solution	12/22/20
Neos Therapeutics, Inc.	Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablets)	7/28/20
Neos Therapeutics, LP	Adzenys XR-ODT (amphetamine extended-release Orally Disintegrating Tablets) 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg & 18.8 mg	12/18/20
Pacira Pharmaceuticals, Inc.	Exparel (bupivacaine liposome injectable suspension)	11/4/20
Portola Pharmaceuticals, Inc.	Bevyxxa (betrixaban)	8/14/20
Salix Pharmaceuticals, Inc.	Trulance (plecanatide) tablet	9/17/20
Shield Therapeutics (UK) Ltd.	Accrufer (ferric maltol)	11/24/20
Vanda Pharmaceuticals, Inc.	Fanapt (iloperidone) tablets	10/1/20

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

Pediatric Advisory Committee (PAC)
September 17, 2021

DRAFT 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
	Clarifying Questions	
11:00 a.m.	Sponsor Presentation • FLOURISH Pediatric Esophageal Atresia Device (HDE)	**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 Surgeon University of Chicago Medicine Comer Children's Hospital
	Clarifying Questions	
11:30 a.m.	**OPEN PUBLIC HEARING**	
12:30 p.m.	**LUNCH**	
1:00 p.m.	*Committee Discussion and Vote*	
3:00 p.m.	**ADJOURNMENT**	**Kelly Wade, MD,** Chairperson, PAC