

Pediatric Advisory Committee Opening Remarks



Dionna J. Green, MD, FCP

Director

Office of Pediatric Therapeutics (OPT)
Office of Clinical Policy and Programs (OCP)
Office of the Commissioner (OC)
Food and Drug Administration (FDA)

September 19, 2023

Opening Remarks

- Personnel Updates
- Pediatric Research Equity Act (PREA) Non-Compliance Letters

Outgoing PAC Members (as of June 2023)



**Kelly Wade,
MD, PhD, MSCE
Neonatal-Perinatal Medicine
University of Pennsylvania
Children's Hospital of
Philadelphia**



**Wael Sayej,
MD, MBA, FAAP
Pediatric Gastroenterology
Baystate Children's Specialty Center**

www.fda.gov



**Benjamin Wilfond,
MD
Pediatric Pulmonology and Bioethics
University of Washington**

PAC Chairperson



**Robert Dracker,
MD, MHA, MBA, CPI
Pediatrics
SUNY Upstate Medical Center**

New PAC Members (Term: 2023-2027)

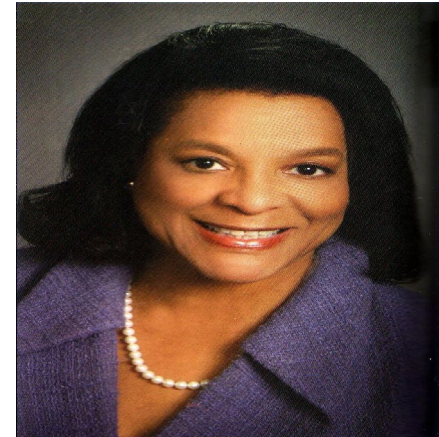


**Susan Baker,
MD, PhD
Pediatric Gastroenterology
University of Buffalo
The State University of New
York**



**Douglas Diekema,
MD, MPH
Pediatric Emergency Medicine and Bioethics
University of Washington**

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**Charleta Guillory,
MD, MPH
Neonatal-Perinatal Medicine
Texas Children's Hospital
Baylor College**

Office of Pediatric Therapeutics – New Staff



**Alison Griffin,
BS
Program Analyst/COI Specialist
Pediatric Advisory Committee Logistics Team**



**Mohamed Mohamoud,
PharmD, MPH
Senior Clinical Analyst
Pharmacovigilance Team**

PREA Non-Compliance Letters

- Center for Biologics Evaluation and Research (n=6)
 - <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/prea-non-compliance-letters>
- Center for Drug Evaluation and Research (n=152)
 - <https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act>
- 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)

PREA Non-Compliance Letters

- Center for Biologics Evaluation and Research (n=6)
 - 3 new letters since the last Pediatric Advisory Committee Meeting
- Center for Drug Evaluation and Research (n=152)
 - 24 new letters since the last Pediatric Advisory Committee Meeting

Non-Compliance Letters (CBER)

Sponsor	Product	Date of Letter
Wyeth Pharmaceuticals, Inc	Trumenba (Meningococcal Group B Vaccine)	7/8/21
OCTAPHARMA Pharmazeutika Produktionsges.m.b.H.	von Willebrand Factor/Coagulation F VIII Complex	9/8/21
Medexus Pharma, Inc	Coagulation Factor IX (Recombinant)	1/25/22

Non-Compliance Letters (CDER)

Sponsor	Product	Date of Letter
KVK-Tech	Apadaz (benzhydrocodone and acetaminophen) tablets	9/7/21
Zyla	Sprix (ketorolac tromethamine) nasal spray	9/8/21
Salix	Xifaxan (rifaximin) tablets	9/13/21
Endo	Opana ER (oxymorphone hydrochloride) extended-release tablets	10/12/21
Supernus	Oxtellar XR (oxcarbazepine) extended-release tablets	10/15/21
Vifor	Veltassa (patiomer) powder for oral suspension	10/15/21
CMP	CaroSpir (Spironolactone) oral suspension	11/5/21
Chartwell	LymePak (doxycycline hyclate) tablets	11/17/21
Benuvia	Syndros (dronabinol) oral solution	12/16/21
SK Life Science	Xcopri (cenobamate) tablets	12/17/21
Primus Pharmaceuticals Inc	Sernivo (betamethasone dipropionate) topical spray	3/16/22
Salix Pharmaceuticals Inc	Trulance (plecanatide) tablets	6/23/22

Non-Compliance Letters (CDER)

Sponsor	Product	Date of Letter
Assertio Therapeutics Inc	Cambia (diclofenac potassium) powder for oral solution	09/28/22
Genus LifeSciences Inc	Tivorbex (indomethacin) capsules	9/29/22
Helsinn Healthcare SA	Akynzeo (netupitant and palonosetron) capsules	11/17/22
Esperion Therapeutics, Inc	Nexletol (bempedoic acid) tablets	11/21/22
Esperion Therapeutics, Inc	Nexlizet (bempedoic acid and ezetimibe) tablets	11/21/22
Salix Pharmaceuticals Inc	Trulance (plecanatide) tablets	3/31/23
Mylan Ireland LTD	Arixtra (fondaparinux sodium injection) solution	2/28/23
Nalpropion Pharmaceuticals LLC	Contrave (naltrexone hydrochloride/bupropion hydrochloride) extended-release tablets	4/12/23
Ardelyx Inc	Ibsrela (tenapanor) tablets	4/19/23
Hikma Pharmaceuticals USA, Inc	phenylephrine hydrochloride injection	5/31/23
Hikma Pharmaceuticals USA, Inc	morphine sulfate oral solution and tablets	6/14/23
Chattem, Inc	Allegra-D 12 Hour Allergy and Congestion (fexofenadine hydrochloride; pseudoephedrine hydrochloride) extended-release tablets	7/21/23

