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PEDIATRIC ADVISORY COMMITTEE OPENING REMARKS

*Pediatric Advisory Committee Meeting
April 8, 2019*

Opening Remarks

- Personnel Update
- Web-posted reviews
- Youth Tobacco Cessation: Science and Treatment Strategies Workshop
- Non-Compliance Letters

Personnel Update

- PAC
 - Robert Dracker, MD
 - Mary Cataletto, MD
 - Bridgette Jones, MD
- OPT
 - Judith Cope, MD

Web Posted Reviews

- **Center for Drug Evaluation and Research**

- ACZONE GEL (dapsone)
- AIRDUO RESPICLICK (fluticasone propionate and salmeterol) and ARMONAIR RESPICLICK (fluticasone propionate)
- AVELOX (moxifloxacin hydrochloride)
- CALDOLOR INJECTION (ibuprofen)
- CUBICIN INJECTION (daptomycin)
- DEXILANT (dexlansoprazole)
- EUCRISA OINTMENT (crisaborole)
- LILETTA (levonorgestrel-releasing intrauterine system)
- LYRICA (pregabalin)
- NARCAN NASAL SPRAY (naloxone hydrochloride)
- OFIRMEV (acetaminophen)
- SELZENTRY (maraviroc)
- SPIRIVA RESPIMAT (tiotropium bromide)
- SYMBICORT INHALATION AEROSOL (budesonide/formoterol fumarate dehydrate)
- TARCEVA (erlotinib hydrochloride)
- VELCADE (bortezomib)

- **Center for Biologics Evaluation and Research**

- ADYNOVATE (Antihemophilic Factor [recombinant])
- IXINITY (Coagulation Factor IX [Recombinant])
- EPICEL (cultured epidermal autografts) (Humanitarian Device Exemption [HDE])

- **Center for Devices and Radiological Health**

- FLOURISH™ PEDIATRIC ESOPHAGEAL ATRESIA DEVICE (HDE)
- LIPOSORBER LA-15 SYSTEM (HDE)
- MEDTRONIC ACTIVA DYSTONIA THERAPY (HDE)

Medwatch Safety Alerts for Human Medical Products

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/default.htm>

Youth Tobacco Cessation: Science and Treatment Strategies Workshop

- May 15, 2019
- FDA White Oak Campus, Great Room
- Registration site <https://www.eventbrite.com/e/youth-tobacco-cessation-science-and-treatment-strategies-tickets-56911369438>



I-ACT INSTITUTE FOR ADVANCED CLINICAL TRIALS
FOR CHILDREN

AND

 **Duke Clinical Research Institute**

MAY
15

**Youth Tobacco Cessation:
Science and Treatment
Strategies**

by Stephen McConoughey

Free

[Register](#)

NON-COMPLIANCE LETTERS

- Center for Biologics and Research (n=2)
 - <https://www.fda.gov/aboutfda/centersoffices/officeofmedicinalproductsandtobacco/cber/ucm448393.htm>
- Center for Drug Evaluation and Research (n=31)
 - <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)