

Susan McCune, M.D.  
Director, Office of Pediatric Therapeutics  
Office of the Commissioner, FDA

# **PEDIATRIC ADVISORY COMMITTEE OPENING REMARKS**

*Pediatric Advisory Committee Meeting  
September 20, 2018*



# Opening Remarks

- Personnel Update
- STRIDER Trial
- Advancing the Development of Pediatric Therapeutics (ADEPT) 5 Workshop
- Non-Compliance Letters



# NON-COMPLIANCE LETTERS

- Center for Biologics and Research (n=2)
  - <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm448393.htm>
- Center for Drug Evaluation and Research (n=30)
  - <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)