U.S. FOOD & DRUG ADMINISTRATION

Public Meeting
Pediatric Medical Device Development

Draft Agenda

Monday, August 13, 2018

Meeting Introduction and Process – Why Are We Here?

8:45 am Opening Remarks – FDA

8:55 am Leading the Charge – Welcome and Introduction to the Meeting
Vasum Peiris , MD, MPH – Chief Medical Officer, Pediatrics and Special Populations, CDRH, FDA

Evolution of Pediatric Medicine and Pediatric Medical Devices

9:00 am Audience Poll Question

Big Needs for Growing Children

9:05 am Why We Need Medical Devices for Children

9:30 am Current Landscape of Pediatric Medicine – Pushing the Envelope

9:40 am FDA Numbers and Facts on Pediatric Medical Devices

9:50 am The National Pediatric Collaborative Community
The FDA Collaborative Community Strategic Priority
The Role and Potential of Pediatric Hospitals and Health Systems

10:15 am Question and Answer

10:25 am **Break: 15 minutes**

21st Century Technology for the Fabulous 21 and Under

10:40 am Audience Poll Question

10:45 am Why Size No Longer Matters: The Advent and Potential of Miniature and Nanotechnology

10:55 am Digital Natives: Children are Principal Innovators

11:05 am Pediatrics, To the Future and Beyond!

11:15 am Question and Answer

11:30 am **Lunch Break: 1 hour**

Optimizing Evidence Generation

12:30 am	Audience Poll Question
12:35 pm	**Opening:** Outline Session Topics and Goals *Doug Silverstein, MD* – Medical Officer, CDRH, FDA
12:45 pm	Solutions to Barriers for Pediatric Evidence Generation
12:55 pm	Use of Real World Evidence (RWE): The Vision and Demonstration of National Evaluation System for health Technology (NEST)
1:05 pm	Flexible Regulatory Paradigms - FDA Initiatives and Programs to Support use of Novel Evidence Generation Approaches
1:15 pm	The PEDs (Pediatric Extrapolation for Devices) Team – A Novel Approach to Extrapolation
1:25 pm	Question and Answer
1:35 pm	**Break: 15 minutes**

FDA-Industry Perspectives on Trial Designs

1:50 pm	Audience Poll Question
1:55 pm	Innovative Trial Designs Going Beyond RCT (FDA) Industry Case Example for novel trial design: MiniMed 670
2:15 pm	Modeling and Simulation Study Designs using Modeling and Simulation (FDA) Industry Case Example: Neonatal Head Imaging MRI
2:35 pm	Question and Answer
2:45 pm	***Break: 15 minutes***

Research Networks and Infrastructure

3:00pm	Audience Poll Question
3:05pm	The Potential of Mature Pediatric Specific Registries
3:15 pm	Disease Specific Learning Networks to Generate Clinical Data
3:25 pm	Pediatric Clinical Trial and Product Development Infrastructure

3:45 pm	Question and Answer
4:00 pm	**Public Comment Period**
4:30 pm	**Directed Expert Panel Discussion**
5:25 pm	**Closing Remarks Day 1**

Tuesday, August 14, 2018

Welcome and Recap

8:30 am Welcome and Recap - *Vasum Peiris, MD, MPH* – Chief Medical Officer, Pediatrics and Special Populations, CDRH, FDA

Creating Regulatory Value and Simplicity

8:40 am Audience Poll Question

8:45 am **Opening:** Outline Session Topics and Goals
Eric Chen, MS – Director, HUD and PDC Programs, OOPD, FDA

8:55 am Overview of Pediatric Medical Device Legislation History

9:15 am How the Rare Disease Drug Market Developed: What Can We Learn from Pediatric Drug Development Legislation?

9:25 am Pediatric Device Development Regulatory Landscape on the International Stage

9:35 am Question and Answer

9:45 am ***Break: 15 minutes***
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10:00 Audience Poll Question

10:05 am Importance of International Regulation Harmonization, US FDA/Japan PMDA Partnership

10:15 am Getting a Pediatric Device to Market – Regulatory Challenges and Solutions from the Corporate Experience
Small Company Perspective
Large Company Perspective

10:35 am Challenges and Opportunities in Promoting Legislation for Pediatric Medical Devices

10:45 am Question and Answer

11:00 am **Public Comment**

11:30 am **Lunch Break: 1 hour**

Developing a Supportive Marketplace

12:30 pm Audience Poll Question

12:35 pm **Opening:** Outline Session Topics and Goals
Cara Tenenbaum, JD, MBA – Senior Policy Advisor, CDRH, FDA

12:45 pm	The Same but Different – Commonalities and Distinctions Between the Pediatric Drug and Device Markets – Just the Facts
12:55 pm	BPCA/PREA for Devices? - The Right Incentives for the Right Market
1:05 pm	Financial Strategies/Models for small and large companies: addressing economic challenges
1:15 pm	How does reimbursement impact pediatric device development Public Insurance Perspective Private Insurance Perspective
1:35 am	Question and Answer
1:45 pm	***Break: 15 minutes***
2:00 pm	Show me the Money: Medical Device Innovation Models Investing in Small Companies – Accelerators, Incubators, and Beyond The non-profit/academic medical center model Federal-State-Private partnerships Philanthropic model VC Perspective
2:50 pm	Dear CEOs, What Will Incentivize You to Enter, Sustain and Innovate in the Pediatric Market? – The C-Suite Survey (CEOs for Children)
3:00 am	Question and Answer
3:10 pm	***Break: 10 minutes***

Panel Discussion and Break Out: The Next 10 Years: Steps Toward an Egalitarian System for Adults and Children

3:20 pm	**Directed Expert Panel Discussion**
4:50 pm	Closing Remarks – *Vasum Peiris, MD, MPH* – Chief Medical Officer, Pediatrics and Special Populations, CDRH, FDA