2024 FDA Oncology Center of Excellence Pediatric Advocacy Forum
October 15, 2024 (9am – 1pm ET)

In-Person   **Virtual**
FDA White Oak Campus, Building 31, Great Room   Via Zoom Webinar

AGENDA

8:30 – 9:00am	**Networking** *(for in-person attendees)*
9:00 – 9:15am	**Welcome and Opening Remarks**
Marc Theoret	Deputy Director, OCE
Martha Donoghue	Associate Director for Pediatric Oncology and Rare Cancers, OCE
Nicole Drezner	Deputy Director, DO2
9:15 – 10:00am	**Session 1** **FDA Leadership Panel: Efforts to Promote Pediatric Drug Development**
Martha Donoghue	Associate Director for Pediatric Oncology and Rare Cancers, OCE
Nicole Drezner	Deputy Director, DO2
Pamela Balcazar	Senior Health Scientist, OCE
Najat Bouchkouj	Associate Director for Pediatrics, OTP, CBER
Pallavi Mishra-Kalyani	Deputy Director, DB V
Nicholas Richardson	Deputy Director, DHM2
Haleh Saber	Acting Director, DHOT
Stacy Shord	Deputy Division Director, DCP II
10:00 – 10:45am	**Session 2** **FDA Role in Clinical Trial Design and Conduct and Pediatric Trial Considerations**
Rosane Charlab Orbach	Team Lead, Pediatrics Group, OCP
Elizabeth Duke	Clinical Reviewer, DO2
Brenda Gehrke	Supervisory Pharmacologist, DHOT
Ruby Leong	Team Lead, DCP I
Lauren Price	Team Lead, DCP II
10:45 – 11:15am	**Break**
11:15 – 11:55am	**Session 3** **Patient Advocacy Listening Session** *(Moderated by Martha Donoghue)*
11:55am – 12:40pm	**Session 4** **Recent FDA Pediatric Approvals and Expedited Programs**
Elizabeth Duke	Clinical Reviewer, DO2
Lori Ehrlich	Clinical Team Leader, DHM1
Sonia Singh	Clinical Reviewer, DO2
Kristin Wessel	Clinical Reviewer, DO2
12:40 – 12:55pm	**Q & A and Looking Ahead** *(Moderated by Nicole Drezner)*
12:55 – 1:00pm	**Closing Remarks and Adjourn**

Abbreviations:
CBER, Center for Biologics Evaluation and Research; DB, Division of Biometrics; DCP, Division of Cancer Pharmacology; DHM, Division of Hematologic Malignancies; DHOT, Division of Hematology Oncology Toxicology; DO, Division of Oncology; OCE, Oncology Center of Excellence; OCP, Office of Clinical Pharmacology; OTP, Office of Therapeutic Products.