FDA Public Workshop:

Evaluation of the Safety of Drugs and Biological Products Used During Lactation

April 27-28, 2016

Final Agenda

Day 1 – April 27, 2016

8:00 – 8:30 am	Registration
8:30 – 8:45 am	Welcome and Day 1 Introductions (Lynne Yao, FDA)
8:45 – 9:00 am	Opening Remarks (Janet Woodcock, FDA)
9:00 – 9:30 am	Plenary Opening - Drugs in Breastmilk: Benefits versus Risks (Ruth Lawrence, University of Rochester School of Medicine)

Workshop Session 1 – What do we currently know? (Melissa Tassinari, Session Chair)

9:30 - 9:50 am	Teresa Baker, Texas Tech University Title: The Benefits of Breastfeeding
9:50 – 10:10 am	Marie Teil, UCB Pharma, Ltd. Title: What Do We Currently Know? An Example from Industry
10:10 – 10:25 am	Tamara Johnson, FDA Title: FDA Perspectives
10:25 – 10:40 am	BREAK

Workshop Session 2 – What we would like to know (Lynne Yao, Session Chair)

10:40 – 11:00 am	Jason Sauberan, Sharp Neonatal Research Institute Title: Absent Friends: The Missing Medications We Wish Were Here
11:00 - 11:20 am	Tacey White, Aclairo Pharmaceutical Development Group, Inc. Title: Nonclinical Studies – What animal studies can (and can't) tell us about drugs in milk
11:20 – 11:40 am	Zhaoxia Ren, NIH

Title: Research on Drugs in Pregnancy and Lactation at NIH

11:40 am – 12:00 pm Mary Short, Eli Lilly and Company
Title: Roadblocks to Clinically Relevant Information Regarding Drug Use and Lactation

12:00 – 1:00 pm Lunch

1:00 – 2:00 pm Q&A

Workshop Session 3 – Communication and Outreach (Tamara Johnson, Session Chair)

2:05 – 2:25 pm Andrew Plumer, National Library of Medicine/LactMed
Title: LactMed Outreach Activities for the Professional and Consumer

2:25 – 2:45 pm Sarah Reece-Stremtan, Academy of Breastfeeding Medicine
Title: Physician to Physician Education in the 21st Century

2:45 – 3:00 pm BREAK

3:00 – 3:20 pm Marsha Walker, United States Lactation Consultant Association
Title: Communicating About Medication Use in 140 Characters or Less

3:20 – 3:40 pm Christina Chambers, University of California San Diego
Title: MotherToBaby Services for Counseling on Exposures in Breastfeeding: When More TLC is Needed

3:40 – 4:10 pm Q&A

4:10 - 4:30 pm Day 1 Wrap-Up (Melissa Tassinari, FDA)

4:30 – 4:40 pm End of Day 1 Logistics

Day 2 – April 28, 2016

8:00 - 8:15 am Welcome, Day 2 Opening Remarks and Recap of Day 1
(Lynne Yao, FDA)

8:15 – 9:00 am Public Comment Session

Workshop Session 4 –How do we get what we don't have? (Leyla Sahin, Session Chair)

9:00 – 9:25 am	Mary Hebert, University of Washington Title: Lactation Study Basics Lessons Learned
9:25 – 9:50 am	Philip Anderson, University of California San Diego Title: Modeling Drug Passage into Breastmilk
9:50 – 10:10 am	Christina Chambers, University of California San Diego Title: Human Milk Biorepository
10:10 – 10:25 am	BREAK
10:25 – 10:45 am	Robert Nelson -FDA Title: Ethical Considerations in the Design and Conduct of Clinical Lactation Studies
10:45 – 11:05 am	Jeffrey Simpson, UCB Biosciences, Inc. Title: An Industry Perspective on Conducting a Lactation Study
11:05 – 11:35 am	Teresa Baker, Texas Tech University Title: Best Practices for Conducting Clinical Lactation Studies
11:35 – 12:35 pm	Q&A
12:35 – 12:45 pm	Wrap-up and Closing Remarks (Lynne Yao, FDA)