FDA Workshop on Biomarkers of Neurotoxicity
July 23, 2019
FDA White Oak Campus – Building 31 Great Room

8:00 – 8:15 a.m. Registration
8:15 – 8:30 a.m. Welcome Address – Janet Woodcock, Director CDER/FDA

**Biomarkers of Neurotoxicity – Statement of Need**
8:30 – 9:00 a.m. Current approach to regulatory evaluation of preclinical neurotoxicity data – Dan Mellon, FDA/CDER
9:00 – 9:30 a.m. Current preclinical neurotoxicity evaluation paradigm in pharmaceutical development – Ingrid Pardo, Pfizer
9:30 – 10:00 a.m. Overview of the biomarker initiative to identify biological fluid-based indicators of neurotoxicity – William Slikker Jr., FDA/NCTR
10:00 – 10:15 a.m. Q&A on biomarkers of neurotoxicity
10:15 – 10:45 a.m. Break

**Development of Fluid Biomarkers of Neurotoxicity**
10:45 – 11:15 a.m. Advances in blood-based biomarkers of concussion – Jeffery Bazarain, University of Rochester
11:15 – 11:45 a.m. Recent advances in fluidic-biomarkers of CNS toxicity – Syed Z. Imam, FDA/NCTR
11:45 – 12:00 p.m. Q&A on Fluidic biomarkers
12:00 – 1:00 p.m. LUNCH

**Development and Qualification of Imaging Biomarkers of Neurotoxicity**
1:00 – 1:30 p.m. MRI biomarkers of neurotoxicity – Serguei Liachenko, FDA/NCTR
1:30 – 2:00 p.m. Correlations of histopathology with MRI – Joseph Hanig, FDA/CDER
2:00 – 2:30 p.m. Overview of biomarker qualification tools and procedures – Jana Delfino, FDA/CDER
2:30 – 2:45 p.m. Q&A on Development and Qualification of imaging biomarkers
2:45 – 3:00 p.m. Summation of all presentations – Dan Mellon, FDA/CDER
3:00 – 4:00 p.m. Roundtable Discussion – Overall perspectives and future directions led by William Slikker, Jr., FDA/NCTR
4:00 p.m. ADJOURN