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**