U.S. FOOD & DRUG ADMINISTRATION

FDA Genetic Toxicology Workshop
How many doses of an Ames-positive/Mutagenic (DNA Reactive) Drug can be safely administered to Healthy Subjects?
November 4, 2019
FDA White Oak Campus – Building 2 (CSU), Room 2031

8:00 – 8:30 a.m.	Registration
Presentations	
8:30 – 9:00 a.m.	Introduction: How many doses of an Ames-Positive (DNA Reactive) Drug can be safely administered to Healthy Subjects? Dr. Timothy W. Robison, CDER, FDA
9:00 – 9:25 a.m.	FDA Requirements for the Protection of Healthy Subjects in Phase 1 Clinical Trials Dr. Kevin Prohaska, CDER, FDA
9:30 – 9:50 a.m.	Considerations for a Genotoxic API in Clinical Trials: Healthy Subjects or Patients? Dr. Bob Dorsam, CDER, Office of Generics, FDA
9:50 – 10:35 a.m.	Literature review for data relevant to administering one or a few doses of a DNA reactive drug to healthy subjects Drs. Dayton Petibone and Jennifer Shemansky, NCTR, FDA
10:35 – 10:50 a.m.	**Break**
10:50 – 11:25 a.m.	Do the Steps between Genotoxin and Cancer Create Thresholds of Dose or Time? Dr. Douglas Brash, Yale University
11:25 a.m. – Noon	Setting Allowable Exposures to Ames-positive Candidate Drugs Dr. Kenny Crump, Louisiana Tech University
12:00 – 1:00 p.m.	**LUNCH**

Panel Discussion

1:00 – 4:00 p.m.

Moderator	Dr. Aisar Atrakchi CDER, FDA
Panelists	
-	Dr. Alan Boobis Professor of Toxicology (emeritus), Imperial College London
-	Dr. Douglas Brash Professor of Therapeutic Radiology and Dermatology, Yale University
-	Dr. Kenny Crump Professor of Mathematics and Statistics, Louisiana Tech University
-	Dr. Robert Heflich Director, Division of Genetic and Molecular Toxicology National Center for Toxicologic Research, FDA
-	Dr. Timothy McGovern Office of Drug Evaluation, Associate Director of Pharmacology and Toxicology, CDER, FDA
-	Dr. Miriam C. Poirier Scientist Emeritus, National Cancer Institute, NIH
-	Dr. Kevin A. Prohaska Captain (U.S. Public Health Service Corps): Senior Medical Policy Advisor/Bioethics Consultant, FDA
-	Dr. Errol Zeiger Private Consultant/Formerly of the National Toxicology Program
4:00 p.m.	**ADJOURN**