2012 FDA Science Writers Symposium Agenda

Monday, September 10, 2012
FDA White Oak Campus, 10903 New Hampshire Avenue, Silver Spring, Md. 20993

MORNING SESSION (9:00 am – 12:00 pm) Great Room, Building 31		
9:00 am – 9:15 am	Introduction	**Welcome:** Steven Immergut, Assistant Commissioner for Public Affairs, Office of External Affairs **Science at FDA:** Jesse Goodman, M.D., M.P.H., FDA's Chief Scientist
9:15 am – 10:00 am	Session 1	**<u>The Promise of "Omics" Research to Improve Drug Safety</u>** **Immuno-proteomics and Ziagen (abacavir) - Understanding the Role of HLA in Serious Drug Adverse Reactions:** Michael Norcross, M.D., Division of Therapeutic Proteins, Office of Biotechnology Products, Center for Drug Evaluation and Research (CDER) **Immune System Responses to Therapeutic Proteins - The Promise of Personalizing Therapies through Pharmacogenomics:** Zuben Sauna, Ph.D., Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER)
10:00 am – 10:30 am	Session 2	**Gene Therapy - Sneaking Genes Past the Body's Defenses** Andrew Byrnes, Ph.D., Office of Cellular, Tissue and Gene Therapies, CBER
10:30 am – 10:45 am	Break/Exhibits	**Exhibits**: FDA's History Office
10:45 am – 11:15 am	Session 3	**Neural Interfaces - Ensuring the Long-Term Reliability of Brain-Computer Interfaces to Control Robotic Devices for Paralyzed Patients**: Cristin Welle, Ph.D., Office of Science and Engineering Laboratories, Center for Devices and Radiological Health
11:15 am – 12:00 pm	**Keynote and News Event**	**Employing Science to Prevent the Growing Risk of Counterfeit and Adulterated Products:** FDA Commissioner Margaret Hamburg, M.D.; R.D. Satzger, Ph.D., Director, FDA's Forensic Chemistry Center (FCC), Cincinnati, Ohio; Nicola Ranieri, Biologist, FCC; Leigh Verbois, Ph.D., Acting Assistant Commissioner for Compliance Policy, Office of Regulatory Affairs
LUNCH AND LAB TOURS (12:00 pm – 3:00 pm) Building 66		
12:00 pm – 3:00 pm	Lunch, Lab Tours, and Filing	**Lab Tours**: CDRH and CDER Laboratories
AFTERNOON SESSION (3:00 pm – 4:30 pm) Great Room, Building 31		
3:00 pm – 3:30 pm	Session 4	**Application of the Antiviral Information Management System (AIMS) Database to Inform Hepatitis C Clinical Trials:** Jeffry Florian, Ph.D., Office of Clinical Pharmacology, CDER; Wendy Carter, D.O., Division of Antiviral Products, CDER
3:30 pm – 4:30 pm	Session 5	**<u>Scientific Computing</u>** **FDA IT and Informatics Transformation**: Eric Perakslis, Ph.D., Chief Information Officer and Chief Scientist (Informatics) **Innovation Pathway 2.0**: Anjali Kataria, M.P.P., Entrepreneur in Residence and Senior Advisor, CDRH **Scientific Enclaves - Harnessing FDA's Vast Clinical Databases to Further Public Health**: Vicki Seyfert-Margolis, Ph.D., Senior Advisor for Science and Innovation and Policy

2012 FDA Science Writers Symposium Agenda

Tuesday, September 11, 2012
FDA White Oak Campus, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Great Room, Building 31		
9:00 am – 9:30 am	Session 1	**Using Decision Analysis Tools to Create a Benefit-Risk Framework for Assessing New Drugs**: Theresa Mullin, Ph.D., Associate Director for Planning and Informatics, CDER
9:30 am – 10:00 am	Session 2	**Research Post 9/11: FDA's Work on Medical Countermeasures**: Luciana Borio, M.D., Assistant Commissioner for Counterterrorism Policy
10:00 am – 10:30 am	Session 3	**Vaccine Adjuvants: Predicting Their Safety Using New Methods and Biomarkers**: Hana Golding, Ph.D., Chief, Lab of Retrovirus Research, Division of Viral Products, CBER
10:30 am – 10:45 am	Break	
10:45 am – 11:00 am	Session 4	**Centers for Excellence in Regulatory Science and Innovation (CERSI) at Georgetown University and the University of Maryland:** Ross Filice, M.D., Office of the Chief Scientist, FDA; Ira Shoulson, M.D., Georgetown University CERSI; James Polli, Ph.D., University of Maryland CERSI
11:00 am – 11:30 am	Session 5	**How Science Informs Regulation of the Family Smoking Prevention and Tobacco Control Act**: David Ashley, Ph.D., Director, Office of Science, Center for Tobacco Products (CTP)
11:30 am – 12:15 pm	Session 6	***Salmonella* Research** **Prevalence, Persistence, and Infiltration of *Salmonella* in East-Coast Tomato Production Environments**: Rebecca Bell, Ph.D., Division of Microbiology, Center for Food Safety and Applied Nutrition (CFSAN) **Developing Rapid Molecular Methods for Detecting *Salmonella* in Animal Feed and Pet Food**: Beilei Ge, Ph.D., Division of Animal and Food Microbiology, Office of Research, Center for Veterinary Medicine
LUNCH (12:15 pm – 12:30 pm)		
12:15 pm – 12:30 pm	Lunch	
MID-DAY SESSION (12:30 pm – 1:30 pm) Great Room, Building 31		
12:30 pm – 1:00 pm	**Luncheon Keynote**	Michael Taylor, J.D., FDA Deputy Commissioner for Foods
1:00 pm – 1:30 pm	Session 7	**FDA's Response to a Multi-State Outbreak of *Salmonella* Bareilly and *Salmonella* Nchanga Associated with Nakaochi Scrape (Tuna), 2012**: LCDR Kari Irvin, Coordinated Outbreak Response & Evaluation (CORE) Network
CFSAN LAB TOUR (1:45 pm – 3:30 pm)		
1:45 pm – 3:30 pm	Lab Tour	**Lab Tour**: CFSAN Laboratories. The labs are located throughout the Wiley Building, 5100 Paint Branch Parkway, College Park, Maryland. A bus will depart from the circle in front of White Oak, Building 1, at 1:45 pm. At the conclusion of the tour, the bus will be available to take visitors back to White Oak or they can take the Metro (College Park Station is directly across from the Wiley Building).