11th Annual FDA Science Forum: Advancing Public Health Through Innovative Science

WEDNESDAY, April 27, 2005

Level 2 – L Street Bridge
7:30 am - 5:00 pm — **REGISTRATION**

Level 2 – Hall D
7:30am - 8:30pm — **POSTER SETUP**

Level 3 – Ballroom C
8:30 am - 9:00 am — **WELCOME AND OPENING REMARKS**
Lawrence X. Yu, Ph.D., Chair, Science Forum Organizing Committee
Keith Carson, Chairman, Williamsburg BioProcessing Foundation
Norris Alderson, Ph.D, Associate Commissioner for Science, FDA
Lester M. Crawford, D.V.M., Ph.D., Acting Commissioner of Food and Drugs

9:00 am - 10:00am — **KEYNOTE ADDRESS**
Michael O. Leavitt
Secretary of Health and Human Services, U.S. Department of Health and Human Services

Level 2 – Hall D
10:00 am - 10:30 am — ***BREAK***

Level 3 – Ballroom C
10:30 am - 11:30 am — **Special Plenary Lecture: Advancing Health through Innovations in Bioengineering**
Robert S. Langer, D.Sc., Kenneth J. Germeshausen Professor of Chemical and Biomedical Engineering, Massachusetts Institute of Technology

Level 2 – Hall D
11:30 am - 1:00 pm — **Poster Session & Exhibits with Box Lunch**
(Poster Presenters should be available at their posters for this session)

Level 2 – Room 204C
11:30 am - 1:30 pm — **FDA Statistical Association meeting**

1:00 pm - 2:50 pm — **Breakout Sessions 1-6 (concurrent)**

Breakout Session 1: Level 2 - Room 206

Nanomedicine: Nonclinical and Clinical Implications
Co-Chairs: Stanley Brown, D.Eng., Biomaterials Engineer, Office of Science and Engineering Laboratories, CDRH, FDA and Jan Simak, Ph.D., Visiting Scientist, Laboratory of Cellular Hematology, CBER, FDA

1:05 pm — **Nanotechnology Treatment Applications**
Jennifer West, Ph.D., Isabel C. Cameron Professor of Bioengineering, Rice University

1:30 pm — **Nanotechnology and Biomimics**
Thomas J. Webster, Ph.D., Assistant Professor of Biomedical Engineering, Purdue University

1:55 pm — **Nanoparticles and Safety**
Paul C. Howard, Ph.D., Division of Biochemical Toxicology, NCTR, FDA

2:20 pm — **Nanotechnology Diagnostic Applications**
Chad Mirkin, Ph.D., George B. Rathman Professor, Department of Chemistry, Northwestern University

Breakout Session 2: Level 2 - Room 207A

Use of Animal Models of Disease for Preclinical Evaluation of Safety and Efficacy
Co-Chairs: Ronald P. Brown, M.S., DABT, Toxicologist, Division of Biology, CDRH, FDA and Yvonne P. Dragan, Ph.D., Director, Systems Toxicology Division, NCTR, FDA

1:05 pm — **Rodent Models of Cardiopulmonary Diseases in Air Pollution Health Effects Studies**
Urmila P. Kodavanti, Ph.D., Pulmonary Toxicology Branch, Experimental Toxicology Division, National Health and Environmental Effects Research Laboratory, US Environmental Protection Agency, Research Triangle Park, NC

1:30 pm — **Severe Pulmonary Pathology after Intravenous Administration of Adenoviral Vectors in Cirrhotic Rats**
Jeffrey S. Smith, Ph.D., Office of Cellular, Tissue, and Gene Therapies, CBER, FDA

1:55 pm — **Rat Models of Cardiovascular and Renal Disease**
Howard Jacob, Ph.D., Professor of Physiology and Human and Molecular Genetics, Medical College of Wisconsin

2:20 pm — **Animal Models to Predict Human Cancer Chemoprevention**
Ernest T. Hawk, M.D., M.P.H., Director, Office of Centers, Training and Resources, NCI, NIH

WEDNESDAY, April 27, 2005 (continued)

Breakout Session 3: Level 2 - Room 207B

Dose Exposure Response Issues: Biologics vs. Small Molecules
Co-Chairs: Don Stanski, M.D., Scientific Advisor to the Director, CDER, FDA and Mercedes Serabian, M.S., DABT, Chief, Pharmacology/Toxicology Branch, CBER, FDA

1:05 pm	**Dose Response Issues for Small Molecules** Joga Gobburu, Ph.D., Team Leader, Pharmacometrics, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA
1:30 pm	**Dose Response Issues for Biologics** Iftekhar Mahmood, Ph.D., Office of New Drugs (ODEVI), CDER, FDA
1:55 pm	**The Importance of Dose Response for Small Molecules** Raymond Miller, Ph.D., Senior Director, Pharmacometrics, Pfizer Global Research and Development, Pfizer Inc.
2:20 pm	**The Importance of Dose Response for Biologics** James Green, Ph.D., Senior VP, Preclinical & Clinical Development Sciences, Biogen Idec, Inc.

Breakout Session 4: Level 2 - Room 202B

Emerging Techologies For Cancer Diagnosis and Treatment
Co-Chairs: Karen Weiss, M.D., ODE VI, Office of New Drugs, CDER, FDA and Miriam Provost, Ph.D., Deputy Director, Division of General, Restorative, and Neurological Devices, CDRH, FDA

1:05 pm	**Partnering Bioengineering and Genomic Testing** Barbara J. Klencke, M.D., Associate Medical Director, Medical Affairs, Genentech, Inc.
1:30 pm	**Image Guided Interventions for Treatment of Solid Tumors** Jonathan B. Kruskal, M.D., Ph.D., Director, Abdominal Imaging, Beth Israel Deaconess Medical Center, Harvard Medical School
1:55 pm	**Nanoparticles for Molecular Imaging and Targeted Drug Delivery in Oncology and Cardiovascular Disease** Gregory Lanza, M.D., Ph.D., Barnes-Jewish Hospital, Washington University, St. Louis
2:20 pm	**The New Office of Oncology Products in CDER: Changes to Enhance Customer Needs** Steven Galson, M.D., Acting Director, CDER, FDA

Breakout Session 5: Level 2 - Room 202A

The Public Health Significance of Pathogens: BSE/TSE
Co-Chairs: George Graber, Ph.D., Deputy Director, Office of Surveillance and Compliance, CVM, FDA and John M. Hicks, D.V.M., M.P.H., Risk Assessment Project Manager, CFSAN, FDA

1:05 p.m.	**Understanding the Evolving Science of BSE/TSE** Will Hueston, D.V.M., Ph.D., Director, Center for Animal Health and Food Safety, University of Minnesota
1:30 p.m.	**Overview of Regulatory Aspects of BSE/TSE (regarding safety of medical products)** David M. Asher, M.D., Supervisory Medical Officer, CBER, FDA
1:55 p.m.	**Animal Feed Controls for Prevention of BSE** Burt Pritchett, D.V.M., M.S., Veterinary Medical Officer, Division of Animal Feeds, CVM, FDA
2:20 p.m.	**Safety Aspects of Gelatin** Patrick Goossens, President, Gelatin Manufacturers of Europe, Belgium

WEDNESDAY, April 27, 2005 (continued)

Breakout Session 6: Level 2 - Room 201

Challenges in Post-marketing Management of Risk and its Evaluation in the General Population
Co-Chairs: Paul Seligman, M.D., M.P.H., Director, Office of Pharmacoepidemiology and Statistical Science, CDER, FDA and Thomas Gross, M.D., M.P.H., Director, Division of Postmarket Surveillance, CDRH, FDA

1:05 pm	**Industry Perspective on Risk Management** Peter K Honig, M.D.,M.P.H. Executive Vice President, Merck & Co., Inc.
1:30 pm	**FDA Risk Management: Drug Perspective** Florence Houn, M.D., Director, Office of Drug Evaluation III, CDER, FDA
1:55 pm	**FDA Risk Management: Device Perspective** Neal I. Muni, M.D., MSPH, Office of Device Evaluation, CDRH, FDA
2:20 pm	**Research Drug & Device Therapeutics** Robert M. Califf, M.D., Professor of Cardiology, Duke Clinical Research Institute
Level 2 – Hall D ***2:50 pm - 3:20 pm***	***BREAK***
3:20 pm - 5:00 pm	***Twelve Roundtable Discussions with FDA Leaders for the Following Topics:***

Level 2 – Room 201 – Interactive Session 1

Antimicrobial Resistance: "Scientific Issues and Future Challenges"
Moderator: Patrick McDermott, Ph.D., Research Microbiologist, Division of Animal and Food Microbiology, Office of Research, CVM

Discussion Topics:

- Does disease prevention from vaccination decrease resistance?
- What is the potential for antimicrobial resistance gene transfer in commensal organisms?
- What is the impact of antimicrobial resistance monitoring and surveillance on risk assessment?

Panel Members:
John H. Powers, M.D., FACP, FIDSA, Lead Medical Officer for Antimicrobial Drug Development & Resistance Initiatives, ODE IV, CDER
Xing Tang, M.D., Visiting Scientist, CDRH
J. Gene LeClerc, Ph.D., Director, Division of Molecular Biology, Office of Applied Research and Safety Assessment (OARSA), CFSAN
Margaret C. Bash M.D., M.P.H., Medical Officer, Laboratory of Bacterial Polysaccharides, Office of Vaccines Research and Review, CBER
Carl E. Cerniglia, Ph.D., Director, Division of Microbiology, NCTR
Atin Datta, Ph.D., Senior Microbiologist, ORO, Division of Field Science, ORA

Level 2 – Room 202A – Interactive Session 2

Biostatistics and Biometrics: "FDA Biostatistics Programs: Current Challenges and Cutting Edge Issues"
Moderator: Robert O'Neill, Ph.D., Director, Office of Biostatistics, CDER

Discussion Topics:

- How should we design, analyze and interpret microarray data?
- What are the potential methods for controlling and interpreting multiplicity?
- What are the challenges in quantitative risk assessment with animal and human focus?
- What are some of the new study designs and analytical methods being proposed for classifications and predictions for diagnostic test evaluations?
- What are current challenges in statistical methodology for product evaluation?

Panel Members:
Anna Nevius, Supervisory Mathematical Statistician, Biometrics Team Scientific Support Staff, ONADE, CVM
Greg Campbell, Ph.D.; Director, Division of Biostatistics, Office of Surveillance and Biometrics, CDRH
Curtis Barton, Ph.D., Biomedical Statistician, Division of Mathematics, Office of Scientific Analysis and Support (OSAS), CFSAN
Peter A. Lachenbruch, Director, Division of Biostatistics, OBE, CBER
Ralph L. Kodell, Director, Division of Biometry and Risk Assessment, NCTR

WEDNESDAY, April 27, 2005 (continued)

Level 2 – Room 202B – Interactive Session 3

Botanical Drugs and Dietary Supplements: "Scientific Issues and Regulatory Perspectives"
Moderator: Susan Walker, M.D., Supervisory Medical Officer, CFSAN
Guest Speakers: Negash Belay, Ph.D., Consumer Safety Officer, Office of Food Additive Safety, CFSAN and
Linda Pellicore, Ph.D., Supervisory Toxicologist, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, CFSAN

Discussion Topics:

- Does the existence of botanical drugs and dietary supplements pose a compromise to the safety and wholesomeness of the nation's food supply?
- What are the challenges to predicting and monitoring target human and animal safety for consumption of such products?
- What areas of scientific research would best aid FDA regulators in dealing with dietary supplements and botanical drugs?

Panel Members:
Shaw Chen, M.D., Medical Officer, Office of New Drugs, ODE V, CDER
William J. Burkholder, D.V.M., Ph.D., DACVN, Veterinary Medical Officer, Office of Surveillance and Compliance, Division of Animal Feeds, CVM
Dan Lyle, Ph.D., Office of Science and Engineering Laboratories, Division of Biology, CDRH
Julian E. A. Leakey, Ph.D., DABT, Office of Scientific Coordination, NCTR
George Salem, Division of Field Science, ORA

Level 2 – Room 207B - Interactive Session 4

cGMP Compliance and Inspection: "Current Approaches to Regulating Product Quality Through cGMP Oversight"
Moderator: David J. Horowitz, Esq., Director, Office of Compliance, CDER

Discussion Topics:

- How does risk management relate to each Center's inspection activities?
- How do modern quality systems approaches relate to each Center's GMPs?
- How do pre and post market review activities relate to GMP inspectional programs?
- What are the efforts to harmonize GMPs with international regulatory approaches?

Panel Members:
Mai Huynh M.S., Team Leader, Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, CVM
Gladys Rodriguez, Director, Division of Enforcement B, Office of Compliance, CDRH
Joseph Baca, Director, Office of Compliance (OC), CFSAN
Mary Malarkey, Director, Office of Compliance and Biologics Quality, CBER
Rebecca A. Asente, M.S., R.D., Compliance Officer, New Orleans District Office, Southeast Region, ORA

Level 2 – Room 207A – Interactive Session 5

Clinical Trials: "Innovative Trial Designs and Evaluation for Medical Product Development"
Moderator: Douglas C. Throckmorton, M.D., Acting Deputy Director, CDER

The session will highlight critical issues facing each Center, to include:

- How can utilizing animal data enhance trial design and conduct?
- What are current obstacles in pediatric trial design and conduct?
- How will developments in drug safety impact trial design and conduct?

Panel Members:
Elizabeth Luddy, D.V.M., VMO, Office of New Animal Drug Evaluation/ Division of Therapeutic Drugs for Non-Food Animals, CVM
Ron Yustein, M.D., Clinical Deputy Director, Office of Device Evaluation, CDRH
David Acheson, M.D., Chief Medical Officer and Director Office of Food Safety, Defense and Outreach, CFSAN
Cynthia A. Rask, M.D., Director, Division of Clinical Evaluation and Pharmacology/Toxicology, Office of Cellular, Tissue and Gene Therapies, CBER
William Slikker, Jr., Ph.D., Deputy Director of Research, NCTR

WEDNESDAY, April 27, 2005 (continued)

Level 2 – Room 206 – Interactive Session 6

Dermatology: "Modern Approaches to Assess Safety, Irritancy, and Absorption of Topically Applied Substances"
Moderator: Jonathan Wilkin, M.D., Director, Division of Dermatology and Dental Drug Products, CDER

Discussion Topics:

• Can assessing systemic safety, photo safety, and local irritancy using animal studies predict human or target animal risk exposure?

• What's the capability of predictive in-vitro testing to replace animal testing and animal models?

Panel Members:
Guilin Qiao, D.V.M., Ph.D., Pharmacologist, Office of New Animal Drug Evaluation, Division of Therapeutic Drugs for Non-Food Animals, CVM
Stephen P. Rhodes, USPHS, Branch Chief, Plastic and Reconstructive Surgery Devices, Division of General, Restorative and Neurological Devices, Office of Device Evaluation, CDRH
Linda M. Katz, M.D., M.P.H., Director, Office of Cosmetics and Colors, CFSAN
Paul C. Howard, Ph.D., Division of Biochemical Toxicology, NCTR

Level 2 – Room 204C – Interactive Session 7

Genomics and Proteomics: "Translating the Science into Regulatory Decision-Making"
Moderator: Thomas A. Cebula, Ph.D., Director, Office of Applied Research and Safety Assessment, CFSAN

Discussion Topics:

• Is the science adequately established for regulatory applications?

• What are the bottlenecks to facilitate efficient transition into regulatory decision-making?

• What steps are needed to validate new techniques?

Panel Members:
Lawrence Lesko, Ph.D., Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER
Michele C. McGuinness, Ph.D., Biologist, Division of Production Drugs: Swine and Poultry Drugs Team, Office of New Animal Drug Evaluation, CVM
Steven Gutman, M.D., Director, Office of In Vitro Diagnostic Device Evaluation and Patient Safety, CDRH
Konstantin Chumakov, Ph.D., D.Sci., Chief, Laboratory of Methods Development, Division of Viral Products, Office of Vaccines Research and Review, CBER
James C. Fuscoe, Ph.D., Director, Center for Functional Genomics, NCTR
Lawrence D'Hoostelaere, Ph.D., ORA

Level 2 – Room 204B – Interactive Session 8

Immunology: "Host-Product Interactions and Immune Responses"
Moderator: Amy Rosenberg, Ph.D., Director, Division of Therapeutic Proteins, Office of Biotechnology Products, CDER

Discussion Topics:

• What can we learn about unwanted immunogenicity from desired immunogenicity?

• Which animal models can be used to predict unintended immunologic responses?

• Do stem cells or their differentiated progeny either stimulate or suppress immune responses to antigens on their surfaces?

Panel Members:
Mike J. Myers, Research Pharmacologist, CVM
Carolyn Neuland, Ph.D.; Chief, Gastroenterology and Renal Devices Branch, Division of Reproductive, Abdominal, and Radiological Devices, Office of Device Evaluation, CDRH
Dennis M. Hinton, Ph. D., Acting Director, Division of Toxicology, Office of Applied Research and Safety Assessment, Office of Science, CFSAN
Suzanne Epstein, Chief, Laboratory of Immunology and Developmental Biology, Division of Cellular and Gene Therapies, Office of Cellular, Tissue, and Gene Therapies, CBER

WEDNESDAY, April 27, 2005 (continued)

Level 2 – Room 204A - Interactive Session 9

Issues in Manufacturing and Control for Drugs, Biologics, Devices, and Food:
"Manufacturing Process Understanding, PAT, and Pre-Market Review"
Moderator: Ajaz Hussain, Ph.D., Deputy Director, Office of Pharmaceutical Science, CDER

Discussion Topics:
- What are the next steps in progression towards the "Desired State" and anticipated requirements for proceeding to "manufacturing process understanding"?
- How much will manufacturing process understanding impact current FDA quality assessment, including establishment of specification for product quality?
- How can elements of manufacturing science and process control from various industries be shared to develop best practices?

Panel Members:
Dennis M. Bensley Jr., Ph.D., Team Leader, ONADE, CVM
Ann M. Ferriter, Reviewer, Office of Device Evaluation, Division of General and Restorative Devices, CDRH
Don L. Zink, Ph.D., Lead Scientist, Food Processing, Office of Plant and Dairy Foods, CFSAN
Joan C. May, Ph.D., Director, Laboratory of Analytical Chemistry, Office of Vaccines Research and Review, CBER
Jim Dunnie, CSO, Division of Field Investigations, ORA

Level 2 – Room 209A – Interactive Session 10

Microbiology: Molecular Characterization of Micro Organisms to Improve Public Health – "Technology and Issues"

Moderator: Arthur J. Miller, Ph.D., Lead Scientist for Microbiology and Associate Director, Joint Institute for Food Safety and Applied Nutrition, Office of Science, CFSAN

Discussion Topics:
- What is the status of the current characterization technologies?
- Which of upcoming near future characterization technologies will have the most impact?
- What is the potential for these technologies to identify and diagnose pathogenic agents in biologics, foods and implanted devices?
- How will new technologies promote product safety and bioterrorism preparedness?

Panel Members:
Shukal Bala, Ph.D., Lead Microbiologist, Division of Special Pathogen and Immunologic Drug Products, Office of Drug Evaluation IV, CDER
Robert D. Walker, M.S., Ph.D., Director, Division of Animal and Food Microbiology, Office of Research, CVM
Chiu S. Lin, Ph.D., Director, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices, Office of Device Evaluation, CDRH
Hira Nakhasi, Ph.D., Director, Division of Emerging and Transfusion Transmitted Diseases, OBRR, CBER
Mark E. Hart, Ph.D., Division of Microbiology, NCTR
Karen Kreuzer, Science Branch Director, Denver District, ORA

Level 2 – Room 209B – Interactive Session 11

Post Marketing Epidemiological Safety Assessment: Current FDA Approaches and Upcoming Challenges
Moderator: Robert Ball, M.D., M.P.H., Sc.M., Chief, Vaccine Safety Branch, Division of Epidemiology, Office of Biostatistics and Epidemiology, CBER

Discussion Topics:
- How do various FDA Centers weigh different types of evidence from case reports to results from trials, investigations and epidemiologic studies in their ongoing evaluation of the benefits and risks of products?

Panel Members:
Paul Seligman, M.D., M.P.H., Director, Office of Pharmacoepidemiology and Statistical Science, CDER
Victoria Hampshire, V.M.D., Senior Regulatory Officer, Office of Surveillance and Compliance, CVM
Tom Gross, M.D., M.P.H., Director, Division of Post-market Surveillance, Office of Surveillance and Biometrics, CDRH
Debra A. Street, Ph.D., Team Leader, Epidemiology Team, Office of Scientific Analysis and Support, CFSAN
Luke D. Ratnasinghe, Ph.D., Director, Center for Structural Genomics, NCTR

WEDNESDAY, April 27, 2005 (continued)

Level 2 – Room 209C – Interactive Session 12

Toxicology: "The Role of Regulatory Toxicology in the 21st Century"
Moderator: William T. Allaben, Ph.D. F.A.T.S., Associate Director for Scientific Coordination, Division of Research, NCTR, FDA
National Toxicology Program Liaison, NCTR

Discussion Topics:

•What are the current challenges to novel product safety assessment?

• How can we utilize Toxicogenomics to conduct Risk Assessment?

• How do we assess local and systemic affects of monomer and polymer exposure from implanted materials?

• What are the hurdles to studying the toxicology of nano scale materials?

• Why are other scientific disciplines detracting students from toxicology?

Panel Members:
David Jacobson-Kram, Ph.D., DABT, Associate Director for Pharmacology and Toxicology, Office of New Drugs, CDER
John D. McCurdy, Ph.D., DABT, Regulatory Chemist/Toxicologist, Division of Animal Feeds, Office of Surveillance and Compliance, CVM
Raju Kammula, D.V.M., Ph.D., DABT, Veterinary Medical Officer/Chief Toxicologist, Office of Device Evaluation, CDRH
David G. Hattan, Ph.D., Senior Toxicologist, Office of Food Additive Safety (OFAS), CFSAN
Mercedes Serabian, M.S., DABT, Chief, Pharmacology/Toxicology Branch, CBER

Level 2 – Hall D
5:00 pm - 6:30 pm ***POSTER RECEPTION- Exhibits***

THURSDAY, April 28, 2005

Level 2 – L Street Bridge
7:30 am - 5:00 pm **REGISTRATION**

Level 3 – Ballroom C
8:00 am - 9:00 am **FDA Scientific Achievement Awards Ceremony**

Level 3 – Ballroom C
9:00 am - 10:00 am **Meet the Center Directors**

The Science behind the Headlines: A Conversation with the FDA Center Directors
Moderated by Mark Barnett
Jesse Goodman, M.D., M.P.H., Center for Biologics Evaluation and Research
Lillian J. Gill, D.P.A., Senior Associate Director, Center for Devices and Radiological Health
Steven K. Galson, M.D., M.P.H., Center for Drug Evaluation and Research
Robert E. Brackett, Ph.D., Center for Food Safety and Applied Nutrition
Steven Vaughn, D.V.M., Director, Center for Veterinary Medicine
Daniel A. Casciano, Ph.D., National Center for Toxicological Research
Steve M. Niedelman, Assistant Commissioner for Regulatory Affairs, Office of Regulatory Affairs

Level 2 – Hall D
10:00 am - 10:30 am ***BREAK***

10:30 am - 12:30 pm **Breakout Sessions 7 - 13 (concurrent)**

Breakout Session 7 - Level 2 – Room 206

Integration of Pharmacogenetics and Pharmacogenomics into Drug Development and Clinical Practice
Co-chairs: Janet Woodcock, M.D., Acting Deputy Commissioner for Operations and Daniel A. Casciano, Ph.D., Director, NCTR, FDA

10:40 a.m. **Pharmacogenetics in Drug Discovery and Treatment**
Jeffrey M. Drazen, M.D., Editor-in-Chief, NEJM, Professor of Medicine, Harvard Medical School

11:05 a.m. **Pharmacogenomics and Molecular Epidemiology**
Fred F. Kadlubar, Ph.D., Director, Division of Molecular Epidemiology, NCTR, FDA

11:30 a.m. **Use of Pharmacogenomics and Pharmacogenetics in Clinical Drug Development**
Allen D. Roses, M.D., Senior Vice President, Genetics Research, GlaxoSmithKline

11:55 a.m. **Translation of Pharmacogenomics and Pharmacogenetics: A Regulatory Perspective**
Lawrence Lesko, Ph.D., Director, Office of Clinical Pharmacology and Biopharmaceutics, CDER, FDA

THURSDAY, April 28, 2005 (continued)

Breakout Session 8 - Level 2 – Room 207A

Predictive Models for Bioavailability and Effectiveness
Co-Chairs: Steven Galson, M.D., Acting Director, CDER, FDA and Marlene E. Haffner, M.D., M.P.H., Rear Admiral/USPHS, Director, Office of Orphan Products Development, FDA

10:40 a.m.	**Predicting Oral Drug Absorption and Bioavailability: Fiction and Facts** Gordon L. Amidon, Ph.D., Charles Walgreen, Jr., Charles Walgreen, Jr., Professor of Pharmacy, University of Michigan
11:05 a.m.	**Predicting Drug Metabolism and Drug-Drug Interactions** Jerry Collins, Ph.D., Director, Division of Clinical Pharmacology Research, CDER, FDA
11:30 a.m.	**Biosimulation of Human Physiology & Pathophysiology - Cells to Clinical Response** Mikhail Gishizky, Ph.D., Chief Scientific Officer, Entelos
11:55 a.m.	**Molecular Modeling and Computer Simulation in the Characterization of Vaccines and Adjuvants** Richard Pastor, Ph.D., Chief, Laboratory of Biophysics, CBER, FDA

Breakout Session 9 - Level 2 – Room 207B

Clinical Biomarkers in Biologics and Drug Development: Efficacy Assessment and Pharmacodynamics
Co-Chairs: Robert Temple, M.D., Director, Office of Medical Policy, CDER, FDA and Peter Lachenbruch, Ph.D., Director, Division of Biostatistics, CBER, FDA

10:40 a.m.	**Biomarkers for Inflammation, Atherosclerotic Vascular Disease and Plaques** Steven Nissen, M.D., Vice Chairman, Professor of Medicine, The Cleveland Clinic Foundation
11:05 a.m.	**Biomarkers as Endpoints in the Study and Treatment of Cancer** Thomas Fleming, Ph.D., Professor, Dept. of Biostatistics, University of Washington
11:30 a.m.	**Considerations in Evaluation of Surrogate Endpoints in Clinical Trialse** Victor De Gruttola, ScD, Harvard School of Public Health
11:55 a.m.	**FDA History/Experience in Use of Biomarkers in Adjudicated Studies** Robert Temple, M.D., Director, Office of Medical Policy, CDER, FDA

Breakout Session 10 - Level 2 – Room 202B

Product Manufacturing Science: Process and Quality Control
Co-Chairs: Steve M. Niedelman, Assistant Commissioner for Regulatory Affairs, ORA, FDA and Helen Winkle, Director, Office of Pharmaceutical Science, CDER, FDA

10:40 a.m.	**Pharmaceutical Manufacturing in the 21st Century** G. K. Raju, Ph.D., Executive Director, MIT/PHARMI MIT Program on the Pharmaceutical Industry, MIT
11:05 a.m.	**Challenges and Opportunities in Enhancement of the CMC Section: Quality - by - Design** Ajaz Hussain, Ph.D., Deputy Director, Office of Pharmaceutical Science, CDER, FDA
11:30 a.m.	**The Case for Manufacturing Science** Gerry Migliaccio, M.S., Vice President, Global Quality Operations, Pfizer Inc.
11:55 a.m.	**Risk Based CMC Assessment** John E. Simmons, Ph.D., Director, Division of New Drug Chemistry I, CDER, FDA

THURSDAY, April 28, 2005 (continued)

Breakout Session 11 - Level 2 – Room 202A

Genetically Engineered Food
Co-Chairs: Adele Turzillo, Ph.D., Biologist, CVM, FDA and Kathleen Jones, Ph.D., Consumer Safety Officer, Office of Regulations and Policy, CFSAN, FDA

10:40 a.m.	**FDA Oversight of Foods Derived from Genetically Engineered Plants and Animals** Eric Flamm, Ph.D., Office of the Commissioner, FDA
11:05 a.m.	**Transgenic Food Animals** Kurt Zuelke, Ph.D., USDA
11:30 a.m.	**Assessing the Allergenicity of Food from Genetically Modified Organisms** Richard E. Goodman, Ph.D., Professor, Food Science & Technology, University of Nebraska – Lincoln
11:55 a.m.	**Development and Impact of Golden Rice** Jorge Mayer, Ph.D., Campus Technologies Freiburg, Germany

Breakout Session 12 - Level 2 – Room 201

Emerging Infectious Diseases and Bioterrorism - Preparing for Timely Approval of Safe and Effective Antimicrobiologicals, Vaccines, and Antisera
Co-Chairs: Bill Rodriguez, M.D., Science Director for Pediatrics, Office of Counterterrorism and Pediatrics, CDER, FDA and Carl Cerniglia, Ph.D., Divisional Director of Microbiology, NCTR, FDA

10:40 a.m.	**Development of Therapies for Anthrax Disease: an Example of a Critical Path** Mary Purucker, M.D., Ph.D., Chief, Division of Counterterrorism, Office of Counterterrorism and Pediatric Drug Development, CDER, FDA
11:05 a.m.	**Lethal Factor Inhibition as Adjunct Therapy for Established Anthrax Infection** Jeffrey D. Hermes, Ph.D., Director of Human and Animal Infectious Diseases Research, Merck Research Laboratories
11:30 a.m.	**Scientific Challenges in Evaluation of Vaccines and Antisera as Countermeasures to Anthrax: What do We Know and What do We Need to Know?** Drusilla Burns, Ph.D., Chief, Laboratory of Respiratory and Special Pathogens, Office of Vaccine Research and Review, CBER, FDA
11:55 a.m.	**Priorities in Planning for the Next Influenza Pandemic** Jon McCullers, M.D., Department of Infectious Diseases, St. Jude Children's Research Hospital

Breakout Session 13 - Level 2 – Room 204A&B

Biological Product Safety – Case Studies and Potential Developments
Co-chairs: Keith L. Carson, Williamsburg BioProcessing Foundation, and Carolyn Wilson, Ph.D., Office of Cellular, Tissue and Gene Therapies, CBER, FDA

	Introduction Keith L. Carson, Williamsburg BioProcessing Foundation
10:40 a.m..	**Preclinical Models for Safety Testing: National Toxicology Program Evaluation of the Safety of Retroviral Vectors** Carolyn Wilson, Ph.D., Laboratory of Immunology and Virology, Division of Cellular and Gene Therapies, Office of Cellular, Tissue and Gene Therapies, CBER, FDA
11:05 a.m	**Safety Issues Pertaining to Biologic Follow-On Products** Mark F. Witcher, Ph.D., Pro Re Nata, Inc.
11:30 a.m.	**Characterization of the Derivatized Haemophilus Influenza Type B Polysaccharide Intermediate for PedvaxHIB, and Its Relationship to Product Safety** Qiuwei Xu, Ph.D., Merck Research Laboratory, West Point, PA
11:55 a.m.	**A Case Study: Leachates as the Root Cause of Epoetin-Associated Pure Red Cell Aplasia (PRCA)** Tim Blanc, Centocor, Inc.
	Panel Discussion with Speakers: Discussion Leader, Keith L. Carson, Williamsburg BioProcessing Foundation
	Discussion Topics: • Processes used to address biologics safety issues • Use of pharmacogenomics to identify individuals with product-specific risk factors • Avoiding problems in the future with better characterization methods and more predictive preclinical models

THURSDAY, April 28, 2005 (continued)

Level 2 – Hall D	**12:30 pm - 2:00 pm**	**Posters & Exhibits with Box Lunch**
Level 2 –Room 209C	**12:30 pm - 2:00 p.m.**	**FDA Intercenter Neurotoxicity Working Group meeting**
Level 2 –Room 204C	**12:30 pm - 2:00 p.m.**	**FDA Risk Assessment Working Group meeting**
Level 2	**2:00 pm - 4:00 pm**	**Breakout Sessions 14-19 (concurrent)**

Breakout Session -14 - Level 2 – Room 206

Bioengineering of Cells and Tissues
Co-Chairs: Deborah Hursh, Ph.D., Senior Staff Fellow, Office of Cellular, Tissue and Gene Therapies, CBER, FDA and Lisa Troutman, M.S., D.V.M., Veterinary Medical Officer, Office of New Animal Drug Evaluation, CVM, FDA

2:10 p.m. **Crossroads in Cell Therapy, Gene Therapy, and Tissue Engineering**
Daniel R. Salomon, M.D., Director, Scripps Center for Organ & Cell Transplantation

2:35 p.m. **Progress in Using (registry) Embryonic Stem Cell Lines to Develop Cell Therapies**
Jane Lebkowski, Ph.D., Senior Vice President, Regenerative Medicine, Geron Company

3:00 p.m. **Cellular Tissue and Gene Therapies - Regulatory Challenges of Novel Treatments**
Celia M. Witten, Ph.D., M.D. Director, Office of Cellular, Tissue, & Gene Therapies, CBER, FDA

3:25 p.m. **Engineering Cells, Tissues, and Organs in Biotech Animals: Scientific and Regulatory Challenges**
Larisa Rudenko, Ph.D., CVM, FDA

Breakout Session 15 - Level 2 – Room 207A

Nonclinical Toxicogenomic Studies and Challenges in Molecular Risk Assessment
Co-Chairs: John Leighton, Ph.D., DABT, Senior Advisor for Biotechnology, Office of New Animal Drug Evaluation, CVM, FDA and Syed F. Ali, Ph.D., Senior Biomedical Research Scientist, Head, Neurochemistry Laboratory, Division of Neurotoxicology, NCTR, FDA

2:10 p.m. **Challenges in Molecular Risk Assessment**
David Jacobson-Kram, Ph.D., DABT, Associate Director for Pharmacology and Toxicology, CDER, FDA

2:35 p.m. **Integrating "Predictive" Technologies within a Highly Regulated Drug Development Environment**
Frank Sistare, Ph.D., Executive Director, Dept. of Laboratory Sciences & Investigative Toxicology, Merck Research Laboratories

3:00 p.m. **Transcriptional Profile of Rat Striatum by Serial Analysis of Gene Expression (SAGE): Effects of Methamphetamine Administration**
Jean Lud Cadet, M.D., Chief, Molecular Neuropsychiatry Branch, National Institute on Drug Abuse

3:25 p.m. **Predictive Toxicogenomics – Where Has it Been and Where Is It Going?**
Cindy Afshari, Ph.D., Associate Director, Amgen Inc., Thousand Oaks, CA

Breakout Session 16 - Level 2 – Room 207B

Adaptive Study Designs to Meet Special Challenges in the Measurement of Efficacy and Safety
Co-Chairs: Robert O'Neill, Ph.D., Director, Office of Biostatistics, CDER, FDA and Mary A. Foulkes, Ph.D., Acting Director, Office of Biostatistics and Epidemiology, CBER, FDA

2:10 p.m. **Clinical Use of Adaptive Study Design in the Measurement of Safety and Efficacy**
Jerold Schindler, Dr. PH, Assistant Vice President, Biostatistics and Clinical Information Systems, Wyeth Research

2:35 p.m. **Concepts and Methodology of Adaptive Study Design**
Peter Bauer, Ph.D. , Professor and Department Head, Institute for Medical Statistics – Vienna, Vienna Medical University

3:00 p.m. **Issues and Opportunity of Adaptive Study Design**
Bruce Turnbull, Ph.D., Professor, School of Operations Research and Industrial Engineering, Cornell University

3:25 p.m. **Role of Adaptive Study Design in Clinical (Genomic) Studies**
Sue Jane Wang, Ph.D., Delegate IPRG, Acting Statistics Team Leader and Expert Mathematical Statistician, Division of Biometrics II, Office of Biostatistics, CDER, FDA

THURSDAY, April 28, 2005 (continued)

Breakout Session 17 - Level 2 – Room 202B

Delivery for Drugs and Biologics: Biomaterials Science and Engineering
Co-Chairs: Subhas Malghan, Ph.D., Deputy Director, Office of Science and Engineering Laboratories, CDRH, FDA and Lori A. Love, M.D., Ph.D., Senior Advisor for Clinical Science, ORA, FDA

2:10 p.m. **Novel Technologies for Delivering Insulin and Other Peptide Drugs**
David C. Klonoff, M.D., F.A.C.P. , Medical Director, Mills-Peninsula Health Services, Diabetes Research Institute

2:35 p.m. **Materials Science Aspects of Controlled Drug Delivery Systems**
David Saylor, Ph.D., Division of Chemistry and Materials Sciences, CDRH, FDA

3:00 p.m. **Device Industry Perspective on Systems for Protein Delivery**
Kevin Skinner, Genzyme, Medtronic MiniMed Inc.

3:25 p.m. **Regulatory and Science Issues Associated with Drug Eluting Stents**
Douglas C. Throckmorton, M.D., Acting Deputy Director, CDER, FDA

Breakout Session 18 - Level 2 – Room 202A

Emerging Analytical Technology for Detecting Toxins
Co-Chairs: Dave Wagner, Ph.D., Animal Feeds Research Program Leader, CVM, FDA and Steven Musser, Ph.D., Chief, Instrumentation and Biophysics Branch, CFSAN, FDA

2:10 p.m. **Rapid Toxin Detection Using the 'Lab on a Chip'**
Greg E. Collins, Ph.D., Naval Research Laboratory

2:35 p.m. **Instrument-Based Methods for Multi-Toxin Detection**
John H. Callahan, Ph.D., Research Chemist, CFSAN, FDA

3:00 p.m. **Novel Methods for the Speciation of Metals in Botanical Products**
R. Kenneth Marcus, Ph.D., Department of Chemistry, Clemson University

3:25 p.m. **Molecularly Imprinted Sensors for Food Safety Applications**
George Murray, Ph.D., Principal Professional Scientist, Applied Physics Laboratory, Johns Hopkins University

Breakout Session 19 - Level 2 – Room 201

FDA Leveraging Program
Co-Chairs: Donald Zink, CFSAN, FDA and
Norris Alderson, Ph.D., Associate Commissioner for Science, FDA

2:10 p.m. **Opportunities for Enhancing FDA, Academic and Industrial Science Programs through Partnerships**
Norris Alderson, Ph.D., Associate Commissioner for Science, FDA

2:35 p.m. **Co-development of Pharmacogenomic based Medical Products**
Christopher J. Webster, BVM&S, M.S., Ph.D., MRCVS, Director, Regulatory Strategy and Intelligence, Millennium Pharmaceuticals, Inc.

3:00 p.m. **PQRI and FDA: How Good Science Results in Good Regulation**
Helen Winkle, Director, OPS, CDER, FDA

3:25 p.m. **Researching Practical Effective Approaches to Improving Food Safety during Manufacturing**
Martin Cole, Ph.D., Director, National Center for Food Safety Technology, Illinois Institute of Technology

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5:00 pm **Adjourn - 2005 FDA Science Forum Ends**