FDA

2005 FDA Science Forum

Advancing Public Health Through Innovative Science

April 27–28, 2005

information: www.fda.gov/scienceforum
registration: www.dcscienceforum.org

Washington Convention Center

FDA WilBio PROUS SCIENCE

Letter from the FDA Commissioner

December 1, 2004

Dear Colleagues and Friends:

On behalf of the FDA 2005 Science Forum Organizing Committee it is my pleasure to officially announce the Call for Posters for the 2005 FDA Science Forum. We invite you to join us on April 27-28, 2005, at the Washington Convention Center.

The FDA Science Forum is a unique conference that showcases the broad range of FDA science and its relationship to the agency's public health mission. This annual meeting facilitates communication between FDA scientists and FDA stakeholders and promotes internal and external collaborations.

The 2005 Forum will bring FDA scientists together with representatives from other components of the Department of Health and Human Services, industry, academia, government agencies, consumer and patient advocacy groups, Congress, international constituents, and many other stakeholders. The Science Forum features presentations by leaders of the academic and public health communities, and thereby provides an excellent environment for the open discussion of emerging science, technology, and methodologies, as well as how they can be used to meet the Nation's public health needs.

We look forward to your participation in the 2005 FDA Science Forum. The preliminary program and abstract submission information is available online at www.fda.gov/scienceforum, and registration information at www.dcscienceforum.org.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

11th Annual FDA Science Forum

Advancing Public Health Through Innovative Science

April 27-28, 2005, Washington, DC Convention Center

http://www.fda.gov/scienceforum

PRELIMINARY PROGRAM

FDA 2005 Science Forum Organizing Committee

Lawrence X. Yu (Chair)
Dominick Roselle (Assistant Chair)
Jan Johannessen (Project Manager)

Syed Ali
Mark Avigan
Linda Benjamin
Robert Bronaugh
Richard Diamond
Raafat Fahmy
Suzanne Fitzpatrick
Fred Fry
David Graham
Mark Hart
Kenneth Hastings
Indira Hewlett
John Hicks
Joanne Locke
Dan B. Lye
Donna Mentch
Tom Modric
Carlos Peña
Mary Poos
Lydia Rosas-Marty
George Salem

PLENARY LECTURE:

Advancing Health through Innovations in Bioengineering

Robert Langer, D.Sc.
Germeshausen Professor of Chemical and Biomedical Engineering
Massachusetts Institute of Technology

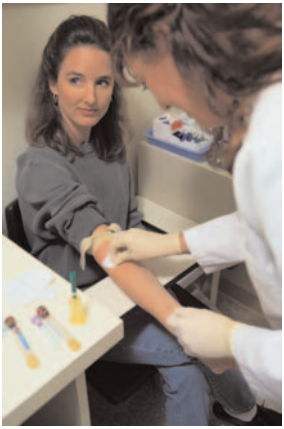
General Sessions:

Innovative Science

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

Integration of Pharmacogenetics and Pharmacogenomics into Drug Development and Clinical Practice
Co-Chairs: Janet Woodcock, M. D., Acting Deputy Commissioner for Operations, FDA and Dan Casciano, Ph.D., Director, National Center for Toxicological Research, FDA

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



General Sessions (continued):

Preclinical Models

Use of Animal Models of Disease for Preclinical Evaluation of Safety & Efficacy

Co-Chairs: Ronald P. Brown, M.S., DABT, Office of Science and Engineering Laboratories, CDRH, FDA and Yvonne P. Dragan, Ph.D., Director, Systems Toxicology Division, NCTR, FDA

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, OC, FDA

Nonclinical Toxicogenomic Studies and Challenges in Molecular Risk Assessment

Co-Chairs: John Leighton, Ph.D., Office of New Drugs, CDER, FDA and Syed F. Ali, Ph.D., Division of Neurotoxicology, NCTR, FDA

Clinical Evaluation

Dose Exposure Response Issues: Biologics vs. Small Molecules

Co-Chairs: Don Stanski, M.D., Scientific Advisor to Director, CDER, FDA and Mercedes Serabian, M.S., DABT, Office of Cellular, Tissue and Gene Therapies, CBER, FDA

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., Office of Biostatistics and Epidemiology, CBER, FDA

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 Susan Ellenberg, Ph.D., Director, Office of Biostatistics and Epidemiology, CBER, FDA

Product Development and Manufacturing

Emerging Technologies for Cancer Diagnosis and Treatment

Co-Chairs: Karen Weiss, M.D., Office of New Drugs, CDER, FDA & Miriam Provost, Ph.D., Division of General, Restorative, and Neurological Devices, CDRH, FDA

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 John Marzilli, Deputy Associate Commissioner for Regulatory Affairs, FDA

Product Manufacturing Science: Process and Quality Control

Co-Chairs: John Taylor, Associate Commissioner Regulatory Affairs, FDA and Helen Winkle, Director, Office of Pharmaceutical Science, CDER, FDA

Food and Animal Feed Safety

The Public Health Significance of Pathogens: BSE/TSE

Co-Chairs: George Graber, Office of Surveillance and Compliance, CVM, FDA and Morrie Potter, Office of Science, CFSAN, FDA

Genetically Engineered Organisms and Food

Co-Chairs: Wendelyn Jones, Ph.D., Office of New Animal Drug Evaluation, CVM, FDA and Kathleen Jones, Ph.D., Office of Regulations and Policy, CFSAN, FDA

Novel Methods for Detecting Toxins in Food and Animal Feeds

Co-Chairs: Dave Wagner, Ph.D., Office of Research, CVM, FDA and Steve Musser, Ph.D., Office of Scientific Analysis and Support, CFSAN, FDA

Public Health

Challenges in Post-marketing Management of Risk and its Evaluation in the General Population

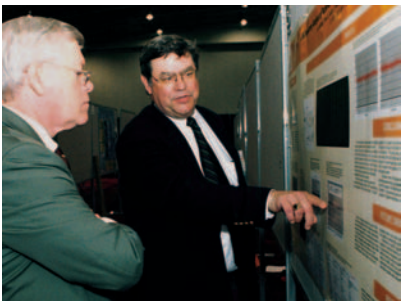
Co-Chairs: Paul Seligman, M.D., M.P.H., Director, Office of Pharmacoepidemiology and Statistical Science, CDER, FDA and Thomas Gross, M.D., M.P.H., Director, Division of Post-Marketing Surveillance, CDRH, FDA

Emerging Contagious Diseases and Bioterrorism - Preparing for Fast Approval of Antimicrobials, Vaccines, and Antisera

Co-Chairs: Carl Cerniglia, Ph.D., Divisional Director of Microbiology, NCTR, FDA and Bill Rodriguez, M.D., Office of Counter-terrorism and Pediatric Development, CDER, FDA

FDA Leveraging Program

Co-Chairs: Robert L. Buchanan, Ph.D., Director, Office of Science, CFSAN, FDA and Norris Alderson, Ph.D., Associate Commissioner for Science, FDA



Meet the Center Directors

The Science Behind the Headlines: a Conversation with the Center Directors, moderated by Mark Barnett

This plenary session will highlight the FDA Center Directors and the Associate Commissioner for Regulatory Affairs. Moderated by Mark Barnett, the session will focus on recent topical issues and utilize a question and answer format to stimulate discussion of the science behind recent FDA actions and future FDA plans. Participants include:

- Jesse Goodman, M.D., M.P.H., Center for Biologics Evaluation and Research
- Daniel Schultz, M.D., Center for Devices and Radiological Health
- Steven K. Galson, M.D., M.P.H., Acting, Center for Drug Evaluation and Research
- Robert E. Brackett, Ph.D., Center for Food Safety and Applied Nutrition
- Stephen F. Sundlof, D.V.M., Ph.D., Center for Veterinary Medicine
- Daniel A. Casciano, Ph.D., National Center for Toxicological Research
- John M. Taylor, Esq., Office of Regulatory Affairs

Interactive Sessions

The interactive sessions are intended as informal, roundtable scientific discussions of topic areas that are both cross-cutting and that present certain conundrums. The purpose of the interactive session is to identify areas of mutual interest, promote interactions, and foster collaboration between FDA scientists and FDA stakeholders. The 1 hour and 40 minute interactive sessions will identify specific discussion topics or questions. Interactive session areas include:

- Issues in Manufacturing and Control for Drugs, Biologics, Devices, and Food
- cGMP Compliance and Inspection
- Botanical Drugs and Nutraceuticals/Dietary Supplements
- Pharmacoepidemiologic Safety Assessment
- Dermatology (Absorption and Cosmetics)
- Genomics/Proteomics
- Clinical Trials
- Toxicology
- Microbiology
- Immunology
- Biostatistics/Biometrics
- Antimicrobial Resistance

FREE Public Session

Personalizing Your Healthcare: The Best Consumer is an Educated Consumer
Tuesday, April 26, 1:00 pm - 5:00 pm
Chaired by Janet Woodcock, M.D., Acting Deputy Commissioner for Operations, FDA

The FDA is committed to increasing health literacy and informing consumers. This free session will provide members of the general public the opportunity to hear about the science behind Personalized Medicine, Generic Drugs and the new Dietary Guidelines, issues of critical importance to the FDA. Presentations will be from national experts in these fields.

"The Importance of Being a Smart Health Consumer"
Harvey Fineberg, M.D., Ph.D., President, Institute of Medicine

Personalized Medicine - What is it? How will it Affect Your Health Care?
Felix Frueh, M.D., Center for Drug Evaluation and Research, FDA and Finley Austin, Ph.D., Personalized Medicine Coalition

Generic Drugs - Are they Really as Good?
Jack Billi, M.D., Associate Vice President, University of Michigan and Gary Buehler, R.Ph., Director, Office of Generic Drugs, CDER, FDA

Are You What You Eat? A Critical Look at the New Dietary Guidelines for Americans, the Science of Nutrition, and Personal Choices for a Healthier Life.
Janet King, Ph.D., R.D., Chair of the Dietary Guidelines Advisory Committee and Barbara Schneeman, Ph.D. Center for Food Safety and Applied Nutrition, FDA

Registration information is available December 1, 2004 at
www.fda.gov/scienceforum

FDA Speakers

Norris Alderson, Ph.D.
Associate Commissioner for Science

Syed F. Ali, Ph.D.
National Center for Toxicological Research

David Asher, M.D.
Center for Biologics Evaluation and Research

Ronald P. Brown, M.S., DABT
Center for Devices and Radiological Health

Stanley Brown, D.Eng.
Center for Devices and Radiological Health

Robert L. Buchanan, Ph.D.
Center for Food Safety and Applied Nutrition

Gary Buehler, R.Ph.
Center for Drug Evaluation and Research

John H. Callahan, Ph.D.
Center for Food Safety and Applied Nutrition

Dan Casciano, Ph.D.
Director, National Center for Toxicological Research

Carl Cerniglia, Ph.D.
National Center for Toxicological Research

Jerry Collins, Ph.D.
Center for Drug Evaluation and Research

Yvonne P. Dragan, Ph.D.
National Center for Toxicological Research

Susan Ellenberg, Ph.D.
Center for Biologics Evaluation and Research

Eric Flamm, Ph.D.
Office of the Commissioner

Felix Frueh, Ph.D.
Center for Drug Evaluation and Research

Steven Galson, M.D.
Center for Drug Evaluation and Research

Joga Gobburu, Ph.D.
Center for Drug Evaluation and Research

Jesse L. Goodman, M.D., M.P.H.
Director, Center for Biologics Evaluation and Research

George Graber, Ph.D.
Center for Veterinary Medicine

Thomas Gross, M.D., M.P.H.
Center for Devices and Radiological Health

Marlene E. Haffner, M.D., M.P.H.
Director, Office of Orphan Products Development

Eugene Herman, Ph.D.
Center for Drug Evaluation and Research

David Horowitz, J.D.
Center for Drug Evaluation and Research

Florence Houn, M.D.
Center for Drug Evaluation and Research

Paul Howard, Ph.D.
National Center for Toxicological Research

Deborah Hursh, Ph.D.
Center for Biologics Evaluation and Research

Ajaz Hussain, Ph.D.
Center for Drug Evaluation and Research

David Jacobson-Kram, Ph.D., DABT
Center for Drug Evaluation and Research

Kathleen Jones, Ph.D.
Center for Food Safety and Applied Nutrition

Wendelyn Jones, Ph.D.
Center for Veterinary Medicine

Fred F. Kadlubar, Ph.D.
National Center for Toxicological Research

Peter Lachenbruch, Ph.D.
Center for Biologics Evaluation and Research

John Leighton, Ph.D.
Center for Drug Evaluation and Research

Larry Lesko, Ph.D.
Center for Drug Evaluation and Research

Iftekhar Mahmood, Ph.D.
Center for Drug Evaluation and Research

Subhas Malghan, Ph.D.
Center for Devices and Radiological Health

John Marzilli
Deputy Associate Commissioner for Regulatory Affairs

Neal Muni, Ph.D.
Center for Devices and Radiological Health

Steve Musser, Ph.D.
Center for Food Safety and Applied Nutrition

Robert O'Neill, Ph.D.
Center for Drug Evaluation and Research

R. Edward Otto, Jr., Ph.D.
Center for Biologics Evaluation and Research

Richard Pastor, Ph.D.
Center for Biologics Evaluation and Research

Morrie Potter, D.V.M.
Center for Food Safety and Applied Nutrition

Burt Pritchett, D.V.M, M.S.
Center for Veterinary Medicine

Miriam Provost, Ph.D.
Center for Devices and Radiological Health

Mary Purucker, M.D., Ph.D.
Center for Drug Evaluation and Research

Bill Rodriguez, M.D.
Center for Drug Evaluation and Research

Larisa Rudenko, Ph.D.
Center for Veterinary Medicine

David Saylor, Ph.D.
Center for Devices and Radiological Health

Barbara Schneeman, Ph.D.
Center for Food Safety and Applied Nutrition

Paul Seligman, M.D., M.P.H.
Center for Drug Evaluation and Research

Mercedes Serabian, M.S., DABT
Center for Biologics Evaluation and Research

Jan Simak, Ph.D.
Center for Biologics Evaluation and Research

Jeffrey S. Smith, Ph.D.
Center for Biologics Evaluation and Research

Don Stanski, M.D.
Center for Drug Evaluation and Research

Robert Temple, M.D.
Center for Drug Evaluation and Research

Douglas Throckmorton, M.D.
Center for Drug Evaluation and Research

Lisa Troutman, M.S., D.V.M.
Center for Veterinary Medicine

Dave Wagner, Ph.D.
Center for Veterinary Medicine

Sue Jane Wang, Ph.D.
Center for Drug Evaluation and Research

Karen Weiss, M.D.
Center for Drug Evaluation and Research

Helen Winkle
Center for Drug Evaluation and Research

Janet Woodcock, M.D.
Acting Deputy Commissioner for Operations

Invited Speakers

Cindy Afshari, Ph.D., Amgen Inc.
Gordon L. Amidon, Ph.D., University of Michigan
Peter Bauer, Ph.D., Institut für Medizinische Statistik, Vienna
Urs Boelsterli, Ph.D., University of Singapore
Jean Lud Cadet, M.D., National Institute on Drug Abuse, National Institutes of Health
Robert M. Califf, M.D., Duke Clinical Research Institute
Martin Cole, Ph.D., Illinois Institute of Technology
Greg E. Collins, Ph.D., Naval Research Laboratory
Victor De Gruttola, Ph.D., Harvard School of Public Health
Jeffrey M. Drazen, M.D., Harvard Medical School
Thomas Fleming, Ph.D., University of Washington
Mikhail Gishizky, Ph.D., Entelos
Patrick Goossens, Gelatin Manufacturers of Europe
James Green, Ph.D., Biogen Idec, Inc.
Jeff Hermes, Ph.D., Merck Research Laboratories
Peter Honig, M.D., M.P.H., Merck
Will Hueston, D.V.M., Ph.D., University of Minnesota
Pamela Klein, M.D., Genentech, Inc.
David C. Klonoff, M.D., F.A.C.P., University of California at San Francisco
Jonathan B. Kruskal, M.D., Ph.D., Harvard Medical School
Howard Jacob, Ph.D., Medical College of Wisconsin
Gregory Lanza, M.D., Ph.D., Washington University
Jane Lebkowski, Ph.D., Geron Corporation
R. Kenneth Marcus, Ph.D., Clemsen University
Jon McCullers, M.D., St. Jude Children's Research Hospital
Gerry Migliaccio, Ph.D., Pfizer Inc.
Chad Mirkin, Ph.D., Northwestern University
George Murray, Ph.D., Johns Hopkins University
Steven Nissen, M.D., The Cleveland Clinic Foundation
G. K. Raju, Ph.D., MIT
Allen D. Roses, M.D., GlaxoSmithKline
Jerry Schindler, Ph.D., Wyeth Research
Frank Sistare, Ph.D., Merck Research Laboratories
Daniel R. Solomon, M.D., Scripps Center for Organ & Cell Transplantation
Steve Taylor, Ph.D., University of Nebraska
Bruce Turnbull, Ph.D., Cornell University
Christopher J. Webster, BVM&S, M.Sc., Ph.D., MRCVS, Millennium Pharmaceuticals, Inc.
Thomas J. Webster, Ph.D., Purdue University
Jennifer West, Ph.D., Rice University
Kurt Zuelke, Ph.D., USDA

Call For ABSTRACTS
Advancing Public Health Through Innovative Science

About the FDA Science Forum Poster Session:
The FDA Science Forum is a unique conference designed to showcase the broad range of FDA science and its relationship to the Agency's public health mission. This annual meeting serves to facilitate communication between FDA scientists and FDA stakeholders and to promote internal and external collaborations. The Sigma Xi Scientific Poster Session is soliciting abstracts from industry/academia/government on all areas related to FDA's Critical Path Initiatives.

Poster Session Critical Path Categories:
A. Biological Endpoints, Biomarkers, Surrogate Markers, & Imaging Technologies
B. Predictive Toxicology: Toxicogenomics and Modeling
C. Predictive Pharmacokinetics and Pharmacodynamics
D. Pharmacogenomics and Proteomics as Product Development Tools
E. Innovative Approaches to Design and Evaluation of Clinical Trials
F. Process Analytical Technology (PAT) and Pharmaceutical Technology
G. Medical Product Design, Characterization, and Manufacturing
H. Risk Management, Risk Assessment, and Risk Communication for Drugs & Food

Criteria For Abstract Submissions:
- Abstracts should address one of the FDA Critical Path areas of interest. (see category list above)
- All abstract submissions are required to be structured using the headings: Purpose, Methods, Results, and Conclusions.
- All submitted abstracts will be peer reviewed by an expert panel for scientific excellence and relevance to FDA's Critical Path initiatives.
- Abstracts **should not** constitute a product advertisement.
- All abstracts will be printed in the 2005 Science Forum Program book and will be posted on the FDA Intranet site and the FDA Sigma Xi Internet site: www.fda.gov/scienceforum
- Authors of accepted abstracts must **register** to attend the Science Forum. Registration information at www.dcscienceforum.org

Non-FDA Abstract Submissions Must Adhere To The Following Guidelines:

1. Submitters will be able to set up an account with login ID and password via the Abstract Submission web site: www.fda.gov/scienceforum. Multiple abstracts may be submitted on an account.
2. Abstracts will be submitted on-line at the above web site; submitted abstracts may be deleted or changed on-line until the abstract submission closes. Submitters will be able to select the appropriate Critical Path related category.
3. The title and authors names and affiliations are entered on the submission form separate from the body of the abstract.
4. The body of the abstracts must be 250 words or less; it may be typed or copy/pasted from a word processor program into the text editor and should use 10 point Regular Times New Roman or Arial font.

5. All abstracts should have the following sections: Purpose, Methods, Results, and Conclusions. It is recommended that these sections be explicitly labeled (see Sample Abstract, below)
6. Text formatting: bold, italic, underlining, subscripts, superscripts, etc., are supported, as are Greek letters and special symbols.
7. An abstract preview will be available once the submission form has been completed.
8. Problems with abstract submission should be addressed to Fred Fry, 301-436-1976, ffry@cfsan.fda.gov

Deadline

The deadline for submission of abstracts is Friday, February 25, 2005.
Abstracts received after this date will be returned.

Contact Info

For additional information, contact:
Fred Fry, at 301-436-1976, ffry@cfsan.fda.gov or
Jan Johannessen, Office of Science and Health Coordination at 301-827-6687, jjohannessen@fda.gov

How Do I Register?

For your convenience and ease of use, we have provided online registration capability by credit. Early registration fees (including all food and beverage/lunch on both days):

Corporate	$595
Corporate single day	$395
Non-Profit	$295
Non-Profit single day	$195
FDA/Other Federal Employee	$25
Students	$25

For registration and fee information go to www.dcscienceforum.org
On line registration will be available December 1, 2004

Where Do I Stay ?

Renaissance Hotel in Washington, DC
Henley Park
Morrison Clark Inn
Grand Hyatt Washington
Marriott Metro Center
Red Roof Inn Downtown
Courtyard Convention Center
The Hotel Monaco
Four Points by Sheraton
Hamilton Crowne Plaza
Hilton Garden Inn
Hotel Sofitel
Washington Plaza
Holiday Inn Downtown
Wyndham Washington, DC
The Madison
Residence Inn Marriot
Hotel Helix
Homewood Suites
Washington Terrace
Capitol Hilton
Holiday Inn Central
Embassy Suites Downtown
Hampton Inn Downtown
Comfort Inn Convention Center
www.dcconvention.com

Department of
Health and Human Services

Food and Drug Administration
Office of the Commissioner
Office of Science and Health Coordination
5600 Fishers Lane, HF-33
Rockville, MD 20857

Official Business
Penalty for Private Use $300

FIRST CLASS MAIL
POSTAGE PAID AND FEES PAID
PHS/FDA
PERMIT NO. G-285