

Center for Drug Evaluation and Research (CDER)
Food and Drug Administration
Department of Health and Human Services

**Generic Drug User Fee Amendments of 2017 Regulatory Science Initiatives:
Request for Public Input for FY 2019 Generic Drug Research
Public Workshop**

Panel Members

Session I: Evaluation of FY 18 Generic Drug Research Priorities

Robert Lionberger, PhD (Moderator)

Director
Office of Research and Standards
Office of Generic Drugs, CDER

Howard Chazin, MD, MBA

Director
Clinical Safety and Surveillance Staff
Office of Generic Drugs, CDER

Andrew Cooper, PhD

Senior Director
Head of Analytical and Materials Science
Mylan Global Respiratory Group

Victor Crentsil, MD, MHS, FCP

Acting Deputy Director
Office of Drug Evaluation III
Office of New Drugs, CDER

Celia Cruz, PhD

Director
Division of Product Quality and Research
Office of Testing and Research
Office of Pharmaceutical Quality, CDER

Sarah Dutcher, PhD, MS

Epidemiologist
Regulatory Science Staff
Office of Surveillance and Epidemiology, CDER

Guenther Hochhaus, PhD

Professor of Pharmaceutics
University of Florida

Julia Kimbell, PhD

Associate Professor
University of North Carolina School of Medicine

Scott E. McNeil, PhD

Director
Nanotech Characterization Lab
Frederick National Laboratory

Mehul Mehta, PhD

Director
Division of Clinical Pharmacology I
Office of Clinical Pharmacology
Office of Translational Sciences, CDER

Thomas Permutt, PhD

Associate Director for Statistical Science and Policy
Office of Biostatistics
Office of Translational Sciences, CDER

Mark Ritter, MD

Associate Director
Division of Clinical Review
Office of Bioequivalence
Office of Generic Drugs, CDER

Michael Roberts, PhD, DSc

Professor of Therapeutics and Pharmaceutical Science
School of Pharmacy and Medical Sciences, University of South Australia
Professor of Clinical Pharmacology and Therapeutics, Diamantina Institute, University of Queensland
Senior Principal Research Fellow with the Australian National Health & Medical Research Council

Amin Rostami, PhD

Professor, University of Manchester
Senior Vice President of R&D and Chief Scientific Officer, Certara

Steven Schwendeman, PhD

Chair and Ara G. Paul Professor of Pharmaceutical Sciences, College of Pharmacy
Professor of Biomedical Engineering, College of Engineering
University of Michigan

Paul Seo, PhD

Director
Division of Biopharmaceutics
Office of New Drug Products
Office of Pharmaceutical Quality, CDER

Stephen Stein, MS

Lead Research Specialist
Inhalation Drug Delivery Group
3M

David Strauss, MD, PhD

Director
Division of Applied Regulatory Science

Office of Clinical Pharmacology
Office of Translational Sciences, CDER

Zhigang Sun, Ph.D.

Vice President
Regulatory Affairs
Sun Pharma

Nilufer Tampal, PhD

Director
Division of Bioequivalence III
Office of Bioequivalence
Office of Generic Drugs, CDER

Katherine Tyner, PhD

Associate Director for Science (Acting)
Office of Pharmaceutical Quality, CDER

Kathleen “Cook” Uhl, MD

Director
Office of Generic Drugs, CDER

Session II: Considerations for FY 19 Generic Drug Research Priorities

Robert Lionberger, PhD (Moderator)

Director
Office of Research and Standards
Office of Generic Drugs, CDER

Bing Cai, PhD

Director
Division of Liquid-Based Products
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality, CDER

Howard Chazin, MD, MBA

Director
Clinical Safety and Surveillance Staff
Office of Generic Drugs, CDER

Celia Cruz, PhD

Director
Division of Product Quality and Research
Office of Testing and Research
Office of Pharmaceutical Quality, CDER

Sarah Dutcher, PhD, MS

Epidemiologist
Regulatory Science Staff
Office of Surveillance and Epidemiology

Guenther Hochhaus, PhD

Professor of Pharmaceutics
University of Florida

Julia Kimbell, PhD

Associate Professor
University of North Carolina School of Medicine

Chris Leptak, PhD

Associate Director for Regulatory Affairs
Office of New Drugs, CDER

Scott E. McNeil, PhD

Director
Nanotech Characterization Lab
Frederick National Laboratory

Mehul Mehta, PhD

Director
Division of Clinical Pharmacology I
Office of Clinical Pharmacology
Office of Translational Sciences, CDER

Thomas Permutt, PhD

Associate Director for Statistical Science and Policy
Office of Biostatistics
Office of Translational Sciences, CDER

Mark Ritter, MD

Associate Director
Division of Clinical Review
Office of Bioequivalence
Office of Generic Drugs, CDER

Michael Roberts, PhD, DSc

Professor of Therapeutics and Pharmaceutical Science
School of Pharmacy and Medical Sciences, University of South Australia
Professor of Clinical Pharmacology and Therapeutics, Diamantina Institute, University of Queensland
Senior Principal Research Fellow with the Australian National Health & Medical Research Council

Amin Rostami, PhD

Professor, University of Manchester
Senior Vice President of R&D and Chief Scientific Officer, Certara

Stephan Schmidt, BPharm, PhD, FCP

Certara Professor
Associate Professor & Associate Director, Center for Pharmacometrics & Systems Pharmacology
Associate Chair, Department of Pharmaceutics Lake Nona (Orlando), University of Florida

Steven Schwendeman, PhD

Chair and Ara G. Paul Professor of Pharmaceutical Sciences, College of Pharmacy
Professor of Biomedical Engineering, College of Engineering
University of Michigan

Paul Seo, PhD

Director
Division of Biopharmaceutics
Office of New Drug Products
Office of Pharmaceutical Quality, CDER

David Strauss, MD, PhD

Director
Division of Applied Regulatory Science
Office of Clinical Pharmacology
Office of Translational Sciences, CDER

Nilufer Tampal, PhD

Director
Division of Bioequivalence III
Office of Bioequivalence
Office of Generic Drugs, CDER

Nicholas Tantillo

Head
Policy and Regulatory Strategy
Sandoz

Katherine Tyner, PhD

Associate Director for Science (Acting)
Office of Pharmaceutical Quality, CDER

Kathleen “Cook” Uhl, MD

Director
Office of Generic Drugs, CDER

Patrick Vallano, Ph.D.

Head
Morgantown R&D
Mylan