Generic Drug User Fee Amendments of 2012 Regulatory Science Initiatives:
Request for Public Input for FY 2016 Generic Drug Research
Part 15 Public Hearing

May 20, 2016
FDA White Oak Campus,
10903 New Hampshire Ave.
Bldg. 31, Rm. 1503
Silver Spring, MD 20993

Agenda

9:00 – 10:00 am — Opening Remarks
Robert Lionberger, Ph.D. — Presiding Officer
Director, Office of Research and Standards
Office of Generic Drugs (OGD), CDER, FDA
"GDUFA Regulatory Science Update"

10:00 – 10:10 am
Michael Fischer, MD., MS
Associate Professor of Medicine
Brigham & Women's Hospital
Harvard Medical School
"Regulatory Science For Generic Drugs"

10:10 – 10:15 am — Questions from Panel

10:15 – 10:25 am
Gordon L. Amidon
Charles R. Walgreen Jr. Professor of Pharmacy & Pharmaceutical Sciences
University of Michigan
"Regulatory Product Research: Oral Systemic Drug Products"

10:25 – 10:30 am — Questions from Panel

10:30 – 10:45 am — Break

10:45 – 10:55 am
Duxin Sun, Ph.D.
Professor of Pharmaceutical Science
The University of Michigan
"Potential New Method To Improve BE Of Modified Release (MR) Drug Products By In Vivo Dissolution Studies In Human GI Tract"

10:55 – 11:00 am — Questions from Panel

11:00 – 11:10 am

Chetan Pujara, Ph.D.
Vice President, Small Molecule Product Development
Allergan
"Non-Biological Complex Drugs: Challenges In The Assessment Of Similarity Or Equivalence Of Ophthalmic Emulsions"

11:10 – 11:15 am Questions from Panel

11:15 – 11:25 am

Catherine M.T. Sherwin, PhD., MSCI., FCP
Assistant Professor, Pediatrics and Pharmacy
Interim Chief Division of Clinical Pharmacology
University of Utah School of Medicine
"Issues Associated With Generic Drugs Used In Children"

11:25 – 11:30 am Questions from Panel

11:30 – 11:40 am

Ajaz S. Hussain, Ph.D.
President, National Institute for Pharmaceutical Technology and Education (NIPTE)
"Confidence In Generics: Need for An Integrated Approach To Formulation Research & Knowledge Management"

11:40 – 11:45 am Questions from Panel

11:45 – 11:55 am

Stephen R. Byrn, Ph.D.
Professor, *National Institute for Pharmaceutical Technology and Education (NIPTE)* and
Purdue University
"Mechanism For An Integrated Approach To Formulation Research, Knowledge Management, & Knowledge Sharing With FDA & Industry"

11:55 am – 12:00 pm Questions from Panel

12:00 – 1:00 pm **Lunch**

1:00 – 1:10 pm

Kenneth R. Morris, Ph.D.
Professor, National Institute for Pharmaceutical Technology and Education (NIPTE) and
Long Island University
"Integrated Approach For Evolving Standards For Formulation Design – Case Example NTI's"

1:10 – 1:15 pm Questions from Panel

1:15 – 1:25 pm

Eric J. Munson, Ph.D.
National Institute for Pharmaceutical Technology and Education (NIPTE) and
Patrick DeLuca Endowed Professor in Pharmaceutical Technology, University of Kentucky
"Integrated Approach For Evolving Standard For Analytical Characterization – Case Example Excipient Variability"

1:25 – 1:30 pm Questions from Panel

1:30 – 1:40 pm
Amy Barton Pai, PharmD, BCPS, FASN, FCCP, FNKF
Professor and Chair, Department of Pharmacy Practice
Director, ANephRx Core Laboratory
Chair, NYS CKD Coalition
Albany College of Pharmacy and Health Sciences
"Relevant Challenges In Determination Of Bioequivalence Of Generic IV Iron Formulations"

1:40 – 1:45 pm Questions from Panel

1:45 – 1:55 pm
Diane J. Burgess, Ph.D.
Board of Trustees Distinguished Professor of Pharmaceutics
University of Connecticut
"In Vitro In Vivo Correlation for Complex Drug Products And In Vitro/In Vivo Stability Issues"

1:55 – 2:00 pm Questions from Panel

2:00 – 2:20 pm
David Gaugh, R.Ph.
Senior Vice President for Sciences and Regulatory Affairs
Generic Pharmaceutical Association (GPhA)
"FY 2017 Regulatory Science Priorities GPhA's Perspective"

2:20 – 2:25 pm Questions from Panel

2:25 – 2:35 pm
Nikunjkumar Patel
Senior Research Scientist
Simcyp(a Certara Company)
"PBPK Modelling In Generic Product Assessment"

2:35 – 2:40 pm Questions from Panel

2:40 – 2:50 pm
Russ Rackley
Global Head, PKDM
Mylan Inc.
"Challenges With The Demonstration Of Statistical Non-Inferiority Of Adhesion & Irritation For Transdermal Drug Delivery Systems Using The OGD Bioguidance Method"

2:50 – 2:55 pm Questions from Panel

2:55 – 3:05 pm
David R. Schoneker
Vice Chair for Scientific and Regulatory Affairs - IPEC Americas
Director of Global Regulatory Affairs – Colorcon
"The Need For Science & Risk-Based Excipient Safety Assessment During Generic Drug Review – Impact On Formulation Quality & Performance"

3:05 – 3:10 pm Questions from Panel

3:10 – 3:25 pm **Break**

3:25 – 3:35 pm
Bahman Asgharian
Research Scientist
Applied Research Associates, Inc.
"Reconstruction Of The Airway Tree, Airflow & Drug Delivery Calculations In The Lungs Of Children With Disease"

3:35 – 3:40 pm Questions from Panel

3:40 – 3:50 pm
Tracy Rupp, PharmD
Director of Public Health Policy Initiatives
National Center for Health Research
"Protecting The Public Health Through Improved Generic Drug Regulation"

3:50 – 3:55 pm Questions from Panel

3:55 – 4:05 pm
James G. Brasseur, Ph.D.
Research Professor*
Aerospace Engineering Sciences, University of Colorado
*also, Professor Emeritus & Adjunct Professor of Mechanical Engineering, Pennsylvania State University
"Importance & Modeling Of Hydrodynamic Effects In Dissolution & Absorption In Vivo vs. In Vitro"

4:05 – 4:10 pm Questions from Panel

4:10 – 4:20 pm
James E. Polli, Ph.D.
Professor and Ralph F. Shangraw
Endowed Chair in Industrial Pharmacy & Pharmaceutics
University of Maryland, School of Pharmacy
"Considerations In Excipients"

4:20 – 4:25 pm Questions from Panel

4:25 – 4:30 pm Closing Remarks
Kathleen "Cook" Uhl, M.D.
Director
Office of Generic Drugs (OGD), CDER, FDA