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Generic Drug User Fee Amendments of 2017 (GDUFA) Science and Research Initiatives:
Request for Public Input on Fiscal Year (FY) 2022 Generic Drug Research
Virtual Public Workshop
June 23, 2021

Agenda

8:00 AM – 8:15 AM	**Opening Remarks**	
	Brenda Stodart, PharmD	Director, CDER SBIA Program, FDA
8:15 AM – 8:20 AM	**Welcome to the 2021 GDUFA Public Workshop**	
	Sally Choe, PhD	Director, OGD, FDA
8:20 AM – 8:35 AM	**Keynote Speaker for the 2021 GDUFA Public Workshop**	
	Janet Woodcock, MD	Acting Commissioner, FDA
8:35 AM – 8:45 AM	**Introduction to the 2021 GDUFA Public Workshop**	
	Robert Lionberger, PhD	Director, ORS, OGD, FDA
	Generic Industry Perspectives:	
8:45 AM – 9:15 AM	***A Summary of Survey Feedback from Industry Stakeholders***	
	James Polli, PhD	Co-Director, CRCG
9:15 AM – 9:45 AM	***A Summary of Interview Feedback from Industry Stakeholders***	
	Anna Schwendeman, PhD	Co-Director, CRCG
9:45 AM – 10:00 AM	***Coffee Break***	
	Generic Industry Challenges #1: *Model-Integrated Evidence for Generic Drug Development*	
10:00 AM – 10:15 AM	***Community Trust in Modelling & Simulation: The Move from Scientific Curiosity to Ingrained Industrial Applications***	
	Amin Rostami, PhD	Prof. of Systems Pharmacology, Univ. of Manchester / CSO, Certara
10:15 AM – 10:25 AM	***Model-Integrated Evidence for Generic Drug Development***	
	Liang Zhao, PhD	Director, DQMM, ORS, OGD, FDA
	Generic Industry Challenges #2: *Complex Product Characterization/Analysis*	
10:25 AM – 10:40 AM	***Complex Product Characterization and Analysis Challenges for Oligonucleotide and Liposomal Drug Products***	
	Zdenko Casar, PhD	Head Early Stage Development Slovenia, Lek Pharm. d.d., Sandoz Pharm.
10:40 AM – 10:50 AM	***Scientific Approaches for the Analytical Characterization of Complex Generic Products***	
	Rachel Dunn, PhD	Director, DPA, OTR, OPQ, FDA
	Generic Industry Challenges #3: *In Vitro & In Vivo BE Approaches: Challenges & Opportunities*	
10:50 AM – 11:05 AM	***Challenges and Opportunities of Complex Clinical Bioequivalence Studies***	
	Beatriz North, MPH	Senior Director, Global Clinical Affairs, Perrigo Pharm.
11:05 AM – 11:15 AM	***Advancing Regulatory Science Through Innovative Bioequivalence Approaches***	
	Partha Roy, PhD	Director, OB, OGD, FDA
11:15 AM – 11:35 AM	**Prepared Public Comments (5 minutes each)**	
11:35 AM – 12:30 PM	***Lunch Break***	
12:30 PM – 1:20 PM	**Generic Industry Perspectives: *A Panel Discussion***	
Moderator:	**Robert Lionberger, PhD**	Director, ORS, OGD, FDA
Panelists:	**James Polli, PhD**	Co-Director, CRCG
	Anna Schwendeman, PhD	Co-Director, CRCG
	Amin Rostami, PhD	Prof. of Systems Pharmacology, Univ. of Manchester / CSO, Certara
	Pradeep Bhadauria, MPharm	CSO, Cipla Pharm.
	Molly Ventrelli, PhD	Senior VP, Regulatory Affairs, Fresenius Kabi
	Janet Vaughn	VP Regulatory Affairs, Teva Pharm.
	Rosario LoBrutto, PhD	Executive Director, Head of Scientific Affairs, Sandoz Pharm.
	Karthik Balasubramanian, PhD	Director, Generic Combination Product Development, Teva Pharm.
	Kiran Krishnan, PhD	Senior VP Global Regulatory and Medical Affairs, Apotex Corp.
	Beatriz North, MPH	Senior Director, Global Clinical Affairs, Perrigo Pharm.
	Zdenko Casar, PhD	Head Early Stage Development Slovenia, Lek Pharm. d.d., Sandoz Pharm.
1:20 PM – 1:30 PM	***Coffee Break***	
1:30 PM – 4:30 PM	**Breakout Sessions (3 Parallel Breakout Sessions; see details below)**	
4:30 PM – 4:45 PM	**Closing Remarks for the 2021 GDUFA Public Workshop**	
	Robert Lionberger, PhD	Director, ORS, OGD, FDA

Breakout Session #1: *Model-Integrated Evidence for Generic Drug Development*

Sub-Session 1A: Discussing the regulatory utility and knowledge gaps related to implementing modeling and simulation (e.g., computational fluid dynamics coupled with physiologically-based pharmacokinetic (PBPK) models for orally inhaled products

1:30 PM – 1:40 PM	***Current Limitations in Producing a Fully Mechanistic PBPK Model for a Highly Soluble Orally Inhaled Drug Product That Exhibits Slow Lung Absorption***	
	Danny Brinkley, BSc	Director, Global Inhalation, R&D, Teva Pharm.
1:40 PM – 1:50 PM	***Integrated Computational Fluid Dynamics-Physiology-Pharmacokinetics Tools for Development and Evaluation of Orally Inhaled Drug Products***	
	Andrzej Przekwas, PhD	CTO, CFD Research Corporation
1:50 PM – 2:20 PM	Panel Discussion (Sub-Session 1A)	
Moderator:	**Andrew Babiskin, PhD**	Team Lead, DQMM, ORS, OGD, FDA
Panelists:	**Danny Brinkley, BSc**	Director, Global Inhalation, R&D, Teva Pharm.
	Andrzej Przekwas, PhD	CTO, CFD Research Corporation
	Guenther Hochhaus, PhD	Prof., Department of Pharmaceutics, Univ. of Florida
	Ross Walenga, PhD	Reviewer, DQMM, ORS, OGD, FDA
	Andrew Cooper, PhD	Head of Analytical Control & Development, Viatris Global Respiratory Group
2:20 PM – 2:30 PM	***Coffee Break***	

Sub Session 1B: Leveraging model integrated evidence for long-acting injectables (LAIs) to reduce regulatory barriers

2:30 PM – 2:40 PM	***Model Integrated Methods for Generic LAI Product Development and Regulatory Assessment: Current Status and Future Research Directions***	
	Andrew Hooker, PhD	Prof. of Pharmacometrics, Uppsala Univ.
2:40 PM – 2:50 PM	***How Can Model Integrated Evidence Accelerate LAI Generic Availability?***	
	Joga Gobburu, PhD	Prof., School of Pharmacy and Medicine, Univ. of Maryland
2:50 PM – 3:20 PM	Panel Discussion (Sub-Session 1B)	
Moderator:	**Lanyan (Lucy) Fang, PhD**	Deputy Director, DQMM, ORS, OGD, FDA
Panelists:	**Andrew Hooker, PhD**	Prof. of Pharmacometrics, Uppsala Univ.
	Joga Gobburu, PhD	Prof., School of Pharmacy and Medicine, Univ. of Maryland
	Liang Zhao, PhD	Director, DQMM, ORS, OGD, FDA
	Keith Gallicano, PhD	Pharmaceutical Consultant
	Xiaoming Xu, PhD	Lab Chief, Branch III, DPQR, OTR, OPQ, FDA
3:20 PM – 3:30 PM	***Coffee Break***	

Sub Session 1C: Exploring opportunities and challenges for utilizing artificial intelligence (e.g., machine learning and natural language processing) to support generic drug development and application assessment

3:30 PM – 3:40 PM	***Artificial Intelligence in Pharmaceutics***	
	Defang Ouyang, PhD	Assistant Professor, Univ. of Macau
3:40 PM – 3:50 PM	***Artificial Intelligence in Generic Drug Development – Experience and Opportunities***	
	Jerneja Opara, PhD	Leading Scientist, Sandoz Pharm.
3:50 PM – 4:00 PM	***Improving Generic Drugs and Streamlining Their Approval Through Artificial Intelligence***	
	Charlie DiLiberti, PhD	President, Montclair Bioequivalence Services, LLC
4:00 PM – 4:30 PM	Panel Discussion (Sub-Session 1C)	
Moderator:	**Meng Hu, PhD**	Team Lead, DQMM, ORS, OGD, FDA
Panelists:	**Defang Ouyang, PhD**	Assistant Prof., Univ. of Macau
	Jerneja Opara, PhD	Leading Scientist, Sandoz Pharm.
	Charlie DiLiberti, PhD	President, Montclair Bioequivalence Services, LLC
	Stella Grosser, PhD	Director, DB-VIII, Office of Biostatistics, OTS, FDA
	Liang Zhao, PhD	Director, DQMM, ORS, OGD, FDA
	Robert Lionberger, PhD	Director, ORS, OGD, FDA
	Donald Mager, PhD	Prof. and Vice Chair, Department of Pharmaceutical Sciences, SUNY
	Robert Bies, PhD	Associate Prof., Department of Pharmaceutical Sciences, SUNY

Breakout Session #2: *Complex Product Characterization/Analysis*

Sub-Session 2A: Exploring potential gaps in complex generic product characterization and analysis

1:30 PM – 1:40 PM	***Industry Perspective on the Gaps in Complex Generic Product Characterization and Future Directions***	
	Rosario LoBrutto, PhD	Executive Director, Head of Scientific Affairs, Sandoz Pharm.
1:40 PM – 2:00 PM	Panel Discussion (Sub-Session 2A)	
Moderator:	**Markham Luke, MD, PhD**	Director, DTP-I, ORS, OGD, FDA
Panelists:	**Rosario LoBrutto, PhD**	Executive Director, Head of Scientific Affairs, Sandoz Pharm.
	Darby Kozak, PhD	Deputy Director, DTP-I, ORS, OGD, FDA
	A Malleswara Reddy, PhD	Head Analytical R&D, Dr. Reddy's Laboratories Limited
	Pahala Simamora, PhD	Director, DLBP-II, OLDP, OPQ, FDA
	Ravi Patel, MS	Assistant VP and Head Of R&D, Cosette Pharm.
	Dama Venugopala Rao, PhD	Analytical Expert, Dr. Reddy's Laboratories Limited
	Ramnarayan Randad, PhD	Branch Chief, Branch II, DLAPI, ONDP, OPQ, FDA
	Kevin Hawkins, PhD	Senior Director, Drug Development R&D Operations (Steriles), Teva Pharm.
2:00 PM – 2:10 PM	***Coffee Break***	

Sub-Session 2B: Discussing new analytical methods that are promising for generic drug development, screening, and evaluation

2:10 PM – 2:20 PM	***Demonstrating Complex Generic Product Equivalence: Benefits & Considerations When Using New Analytical Methods***	
	Darby Kozak, PhD	Deputy Director, DTP-I, ORS, OGD, FDA
2:20 PM – 2:40 PM	Panel Discussion (Sub-Session 2B)	
Moderator:	**Markham Luke, MD, PhD**	Director, DTP-I, ORS, OGD, FDA
Panelists:	**Rosario LoBrutto, PhD**	Executive Director, Head of Scientific Affairs, Sandoz Pharm.
	Darby Kozak, PhD	Deputy Director, DTP-I, ORS, OGD, FDA
	A Malleswara Reddy, PhD	Head Analytical R&D, Dr. Reddy's Laboratories Limited
	Pahala Simamora, PhD	Director, DLBP-II, OLDP, OPQ, FDA
	Ravi Patel, MS	Assistant VP and Head Of R&D, Cosette Pharm.
	Dama Venugopala Rao, PhD	Analytical Expert, Dr. Reddy's Laboratories Limited
	Ramnarayan Randad, PhD	Branch Chief, Branch II, DLAPI, ONDP, OPQ, FDA
	Kevin Hawkins, PhD	Senior Director, Drug Development R&D Operations (Steriles), Teva Pharm.
2:40 PM – 2:50 PM	***Coffee Break***	

Sub-Session 2C: Assessing analytical methods currently considered most useful and how to better develop these technologies

2:50 PM – 3:00 PM	***Analytical Methods to Support Generic Drug Bioequivalence***	
	A Malleswara Reddy, PhD	Head Analytical R&D, Dr. Reddy's Laboratories Limited
3:00 PM – 3:20 PM	Panel Discussion (Sub-Session 2C)	
Moderator:	**Markham Luke, MD, PhD**	Director, DTP-I, ORS, OGD, FDA
Panelists:	**Rosario LoBrutto, PhD**	Executive Director, Head of Scientific Affairs, Sandoz Pharm.
	Darby Kozak, PhD	Deputy Director, DTP-I, ORS, OGD, FDA
	A Malleswara Reddy, PhD	Head Analytical R&D, Dr. Reddy's Laboratories Limited
	Pahala Simamora, PhD	Director, DLBP-II, OLDP, OPQ, FDA
	Ravi Patel, MS	Assistant VP and Head Of R&D, Cosette Pharm.
	Dama Venugopala Rao, PhD	Analytical Expert, Dr. Reddy's Laboratories Limited
	Ramnarayan Randad, PhD	Branch Chief, Branch II, DLAPI, ONDP, OPQ, FDA
	Kevin Hawkins, PhD	Senior Director, Drug Development R&D Operations (Steriles), Teva Pharm.
3:20 PM – 3:30 PM	***Coffee Break***	
3:30 PM – 4:30 PM	Panel Discussion (Overall Breakout Session 2)	
Moderator:	**Markham Luke, MD, PhD**	Director, DTP-I, ORS, OGD, FDA
Panelists:	**Rosario LoBrutto, PhD**	Executive Director, Head of Scientific Affairs, Sandoz Pharm.
	Darby Kozak, PhD	Deputy Director, DTP-I, ORS, OGD, FDA
	A Malleswara Reddy, PhD	Head Analytical R&D, Dr. Reddy's Laboratories Limited
	Pahala Simamora, PhD	Director, DLBP-II, OLDP, OPQ, FDA
	Ravi Patel, MS	Assistant VP and Head Of R&D, Cosette Pharm.
	Dama Venugopala Rao, PhD	Analytical Expert, Dr. Reddy's Laboratories Limited
	Ramnarayan Randad, PhD	Branch Chief, Branch II, DLAPI, ONDP, OPQ, FDA
	Kevin Hawkins, PhD	Senior Director, Drug Development R&D Operations (Steriles), Teva Pharm.

Breakout Session #3: *In Vitro & In Vivo BE Approaches: Challenges & Opportunities*

Sub-Session 3A: Considering the utility of in vitro characterization and modeling approaches to support biowaivers for certain non-Q1/Q2 formulations of prospective generic products

1:30 PM – 1:45 PM	***Mechanistic Assessment of Excipient Changes for Biopharmaceutics Classification System (BCS) 1 Class and 3 Drug Products***	
	Talia Flanagan, PhD	Head of Biopharmaceutics, UCB
1:45 PM – 2:00 PM	***BCS Class 3 Compounds: In Vivo Experience with Non-Q1/Q2 Formulations***	
	Igor Legen, PhD	Head of Clinical Development, Sandoz Pharm.
2:00 PM – 2:50 PM	Panel Discussion (Sub-Session 3A)	
Moderator:	**Heather Boyce, PhD**	Reviewer, DTP-II, ORS, OGD, FDA
Panelists:	**Talia Flanagan, PhD**	Head of Biopharmaceutics, UCB
	Igor Legen, PhD	Head of Clinical Development, Sandoz Pharm.
	Paul Seo, PhD	Director, Division of Biopharmaceutics, ONDP, OPQ, FDA
	Bing Cai, PhD	Director, DLBP-I, OLDP, OPQ, FDA
	Sid Bhoopathy, PhD	President and COO, Absorption Systems
	Fang Wu, PhD	Scientific Lead, DQMM, ORS, OGD, FDA
	Tausif Ahmed, PhD	Director, Global Clinical Management, Dr. Reddy's Laboratories
	Sandra Suarez-Sharp, PhD	VP, Regulatory Affairs, Simulations Plus, Inc.
2:50 PM – 3:10 PM	***Coffee Break***	

Sub-Session 3B: Discussing the design, conduct, and data analysis of in vivo bioequivalence studies, including the study design and the selection of appropriate subject or patient populations, for certain complex products, including oncologic products

3:10 PM – 3:25 PM	***Complexities Involved in Conducting Patient Pharmacokinetic/Pharmacodynamic/Clinical Endpoint Studies and Alternate Proposals to Have Simplified Study Designs***	
	Nageshwar Thudi, PhD	Senior Director, Global Generic/Biosimilar Clinical Dev/Ops, Teva Pharm.
3:25 PM – 3:40 PM	***Clinical Development of Orally Inhaled Products: Bioequivalence Study Designs, Conduct, Subject Attributes and Analysis - Challenges and Opportunities***	
	Bill Brashier, MBBS & DTCD	Group Head, Respiratory Clinical Development, Sandoz Pharm.
3:40 PM – 4:30 PM	Panel Discussion (Sub-Session 3A)	
Moderator:	**Mitchell Frost, MD**	Deputy Director, DTP-II, ORS, OGD, FDA
Panelists:	**Nageshwar Thudi, PhD**	Senior Director, Global Generic/Biosimilar Clinical Dev/Ops, Teva Pharm.
	Siddharth Chachad, MBBS, MSc	EVP & Head, Global Clinical Management, Dr. Reddy's Laboratories Ltd.
	Yu Chung Tsang, PhD	CSO, Biopharmaceutics & Biostatistics, Apotex Inc.
	William Chong, MD	Associate Director for Clinical Affairs, OGD, FDA
	Raja Velagapudi, PhD	Head, Clinical Development, Sandoz Pharm.
	Bill Brashier, MBBS	Group Head, Respiratory Clinical Development, Sandoz Pharm.
	Beatriz North, MPH	Senior Director, Global Clinical Affairs, Perrigo Pharm.
	Kachikwu Illoh, MD	Director, DCR, OSCE, OGD, FDA

Appendix of Abbreviations

BSc	Bachelor of Science
CDER	Center for Drug Evaluation and Research
CRCG	Center for Research on Complex Generics
COO	Chief Operating Officer
CSO	Chief Scientific Officer
CTO	Chief Technical Officer
DB-VIII	Division of Biostatistics VIII
DCR	Division of Clinical Review
Dev/Ops	Development and Operations
DPA	Division of Pharmaceutical Analysis
DQMM	Division of Quantitative Methods and Modeling
DLAPI	Division of Lifecycle Active Pharmaceutical Ingredients
DLBP-I	Division of Liquid Based Products I
DLBP-II	Division of Liquid Based Products II
DPQR	Division of Product Quality Research
DTP-I	Division of Therapeutic Performance I
DTP-II	Division of Therapeutic Performance II
EVP	Executive Vice President
FDA	United States Food and Drug Administration
LLC	Limited Liability Corporation
MBBS	Bachelor of Medicine, Bachelor of Surgery
MPH	Master of Public Health
MPharm	Master of Pharmacy
MD	Doctor of Medicine
OB	Office of Bioequivalence
OGD	Office of Generic Drugs
OLDP	Office of Lifecycle Drug Products
ONDP	Office of New Drug Products
OPQ	Office of Pharmaceutical Quality
ORS	Office of Research and Standards
OSCE	Office of Safety and Clinical Evaluation
OTR	Office of Testing and Research
OTS	Office of Translational Sciences
Pharm.	Pharmaceuticals
PharmD	Doctor of Pharmacy
PhD	Doctor of Philosophy
Prof.	Professor
R&D	Research and Development
SBIA	Small Business Industry Assistance
Sr.	Senior
Univ.	University
VP	Vice President