Presentations Relating to GDUFA Science and Research in Fiscal Year 2023

1. Abdullah A. *Comprehensive Impurities Profiling in Synthetic Oligonucleotides by High-resolution Mass Spectrometry Intact Mass Data Processing.* Presentation at the American Society for Mass Spectrometry (ASMS) - 71st Conference on Mass Spectrometry and Allied Topics. Houston, TX, Jun. 08, 2023.

2. Abdullah A. *Comprehensive Impurity Profiling of Synthetic Oligonucleotides by High-Resolution Mass Spectrometry Intact Mass Data Processing.* Presentation at the American Society of Mass Spectrometry (ASMS) 2023. Houston, Texas, Jun. 07, 2023.

3. Agarwal S. *Excipient Safety Assessment in Generic Drug Formulations: An Overview.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

4. Al Ghabeish M. *Q1 and Q2 Recommendations: Sucralfate Oral Suspension.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 14, 2023.

5. Babiskin A, and Yoon M. *Regulatory Perspective on Modeling Strategies Across Multiple Submissions.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 27, 2022.

6. Babiskin A. *Considerations for Using Model Master Files.* Presentation at the Physiologically based Biopharmaceutics Modeling (PBBM) Best Practices for Drug Product Quality: Regulatory and Industry Perspectives. Rockville, MD, Aug. 30, 2023.

7. Ballard B. *Drug-Device Combination Product Development Simulation.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Drug-Device Combination Products 101: Identifying, Developing, And Evaluating Drug-Device Combination Products. Hybrid Meeting. Rockville, MD, May 10, 2023.

8. Barretto F. *Challenges in Demonstrating API Sameness for Drug Products with Complex APIs.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) 2022: Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 28, 2022.

9. Batchelor H. *Oral PBPK to Support BE Evaluation for Pediatric Drugs.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 27, 2022.

10. Belsey N. *Visualization of Topical Drug Delivery with Label Free Chemical Imaging.* Presentation at the Gordon Research Conference (GRC) - Barrier Function of Mammalian Skin 2023. Waterville Valley, NH, Aug. 10, 2023.

11. Bengtson K. *GDUFA III Redesigned Pre-Submission (PSUB) Meetings.* Presentation at the Small Business and Industry Assistance (SBIA) Webinar - A Deep Dive: GDUFA III Scientific Meetings. Virtual Meeting, May 15, 2023.

12. Bhattad N. *Scientific Challenges Related to Establishing Q1/Q2 Sameness-An Industry Perspective.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

13. Bielski E, Reed N. *Loxapine Inhalation Powder: OTR Research Conducted to Inform the PSG Recommendations.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

14. Bielski E. *Considerations and Challenges for Dissolution Testing of Orally Inhaled Drug Products (OIDPs).* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

15. Bielski E. *Considerations and Challenges for Dissolution Testing of Orally Inhaled Drug Products (OIDPs).* Presentation at the Society for Pharmaceutical Dissolution Science US Chapter Webinar. Virtual Meeting, Apr. 20, 2023.

16. Bielski E. *Emerging Concepts and New Technologies for Bioequivalence of Orally Inhaled and Nasal Drug Products.* Presentation at the American Thoracic Society (ATS) International Conference 2023. Washington, DC, May 22, 2023.

17. Bielski E. *Regulatory Science in the Field of Respiratory Medicine: Current Challenges and New Frontiers with Generics.* Presentation at the 2022 Virginia Commonwealth University Pharmaceutics Seminar. Virtual Meeting, Nov. 04, 2022.

18. Bielski E. *Scientific Careers at FDA: Where Science Meets Regulations and Public Health.* Presentation at the 2022 Virginia Commonwealth University Pharmaceutics Seminar. Virtual Meeting, Nov. 03, 2022.

19. Bielski E. *The Current Status and Considerations for Dissolution Testing of Orally Inhaled Drug Products (OIDPs).* Presentation at the Society for Pharmaceutical Dissolution Science USA (SPDS-US) - Webinar. Virtual Meeting, Sep. 15, 2023.

20. Bies R. *PBPK Modeling Approaches to the Female Reproductive Tract.* Presentation at the Gates Grand Challenge, Non-hormonal Discovery Convening. Brussels, Belgium, Oct. 23, 2022.

21. Boc S. *Complex Nasal Suspension PSGs: Utilization of Newly Recommended In Vitro Only Bioequivalence Option.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

22. Boc S. *Considerations for Conducting More Realistic Aerodynamic Particle Size Distribution Testing for Orally Inhaled Drug Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint

and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

23. Bode C. *Use of a Novel Technology, the In Vitro Dissolution Absorption System, to Investigate the Effects of Antioxidants on the Intestinal Permeation of BCS Class III Drugs.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

24. Bodenlenz M. *Dermal Open-Flow Microperfusion Indicates Differences in Topical Drug Permeation Between Males and Females.* Presentation at the Gordon Research Conference (GRC) - Barrier Function of Mammalian Skin 2023. Waterville Valley, NH, Aug. 09, 2023.

25. Bulitta J. *Feasibility of Predicting Regional Lung Exposure from Systemic Pharmacokinetic (PK) Data of Generic OIDPs via Population PK.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, Maryland, Apr. 21, 2023.

26. Chakraborty S. *REMOVE Approaches in Establishing BE Safe Space for Oral Solid Dosage Form.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) 2022: Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 27, 2022.

27. Chavan M. C*urrent Regulatory Perspective for Demonstrating the Quality and Performance of Proposed Generic Versions of Transdermal Systems, Intravaginal Systems, Implants, and Intrauterine Systems.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG)Drug-Device Combination Products 101: Identifying, Developing, and Evaluating Drug-Device Combination Products. Hybrid Meeting. Rockville, MD, May 10, 2023.

28. Chen K. *2D HSQC Peak Profile Method to Compare Chemical Differences between Batches of Pentosan Polysulfate Sodium.* Presentation at the The 2nd USP qNMR Symposium. Virtual Meeting, Jan. 09, 2023.

29. Chen K. *Direct Assessment of Oligomerization of Chemically Modified Peptides and Proteins in Formulations using DLS and DOSY-NMR.* Presentation at the Analytical Technologies Europe: Symposium on Analytical Sciences and Regulatory Trends in the Biopharmaceutical Industry 2023. Rotterdam, Netherlands, May. 12, 2023.

30. Chen K. *High Resolution 1D and 2D NMR in Complex Drug Analysis: Pentosan Polysulfate Sodium.* Presentation at the Pharmaceutical Analysis and Characterization-Center of Excellence. Virtual Meeting, Mar. 17, 2023.

31. Chen K. *NMR as a Multi-Attribute Method in Complex Drug Analysis: Pentosan Polysulfate Sodium.* Presentation at the 30th Symposium on Glycosaminoglycans. Loveno di Menaggio, Italy, Sep. 21, 2023.

32. Chopski S. *Innovative Technology: Particle Image Velocimetry (PIV) and High Speed Imaging to Support Approval of Generic Orally Inhaled Drug Products.* Presentation at the Small Business and

Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 14, 2023.

33. Clark A. *Correlating Microstructure to Performance of PLGA Microspheres Using X Ray Microscopy and AI Based Image Analysis.* Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 27, 2023.

34. Clarke J. *Utilizing Mechanistic Dermal Absorption Models to Assess Virtual BE.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 27, 2022.

35. Clerman A. *Post-Approval Impact of Generic Fluticasone Propionate & Salmeterol Inhalation Powder (RLD: Advair Diskus).* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 14, 2023.

36. Conrad M. *Insights into the Comparative Use Human Factors Method for FDA Submissions: Results from Interview with Industry Experts.* Presentation at the 12th International Symposium on Human Factors and Ergonomics in Healthcare. Orlando, FL, Mar. 28, 2023.

37. Coppersmith D. *Considerations for Application Pathway: 505(b)(2) or ANDA.* Presentation at the Small Business and Industry Assistance (SBIA) - Generic Drugs Forum (GDF) 2023: Celebrating 10 Years of the GDF. Virtual Meeting, Apr. 12, 2023.

38. Dandamudi S. *Non-Q2 Sucralfate Suspension Approval.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 14, 2023.

39. Das J. *AI-Assisted Regulatory Tool to Improve the Quality and Assessment of PLGA Formulations.* Presentation at the Controlled Release Society 2023 Annual Meeting. Las Vegas, NV, Jul. 24, 2023.

40. De Backer J. *Patient - Specific Aerosol Deposition Assessment - Technology and Validation.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 21, 2023.

41. Dieke N, Shipman J, Sommers C, Rodriguez J, Zhang D, Kozak D, and Yang K. *High-Resolution Ion Mobility Mass Spectrometry in Separation of Oligonucleotide Impurities.* Presentation at the American Society for Mass Spectrometry (ASMS) - 71st Conference on Mass Spectrometry and Allied Topics. Houston, Texas, Jun. 06, 2023.

42. Dubey V. *Development Strategies for Generic Topical Products with Formulation Differences to Reference Listed Drug.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development. Virtual Meeting, Nov. 03, 2022.

43. Ducharme M. *Model Integrated Equivalence for BE Assessment of Long Acting Injectables: In Silico Continuation to Steady State.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) 2022: Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 27, 2022.

44. Ehlert M. *Control Strategies for NDSRIs Originating from Impurity Amines in APIs.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

45. Evans C. *PK and PD Tomography: Imaging and Quantifying Skin Pharmacology.* Presentation at the Gordon Research Conference (GRC) - Barrier Function of Mammalian Skin 2023. Waterville Valley, NH, Aug. 10, 2023.

46. Evans, C. *Cutaneous Pharmacokinetic and Pharmacodynamic imaging with Coherent Raman Scattering.* Presentation at the 2023 SPIE. Photonics West. San Francisco, CA, Jan. 30, 2023.

47. Fan Q, and Harigaya Y. *Cyclosporine & Difluprednate Ophthalmic Emulsions.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

48. Fan Q, and Harigaya Y. *Cyclosporine & Difluprednate Opthalmic Emulsions.* Presentation at the Cyclosporine & Difluprednate Opthalmic Emulsions. Virtual Meeting, Sep. 13, 2023.

49. Fang L. *Model Integrated Evidence for Bioequivalence Evaluation to Support Generic Drug Development and Regulatory Approval.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 28, 2022.

50. Fang L. *Partial Area Under Curve (pAUC): Product-Specific Guidance Development.* Presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2022 Webinar. Virtual Meeting, Oct. 25, 2022.

51. Fanse S. *Enabling the Rational Development of Long-Acting Contraceptive Levonorgestrel Intrauterine Systems.* Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 27, 2023.

52. Feibus K. *Generic Drug-Device Combination Product Research – Focus on Comparative Device User Interface Assessment and Understanding How Differences Impact Users.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Drug-Device Combination Products 101: Identifying, Developing, And Evaluating Drug-Device Combination Products. Hybrid Meeting. Rockville, MD, May 10, 2023.

53. Feibus K. *Research Efforts to Broaden Published Data on User Interface Differences & the Impact on User Error to Support Certain Types of User Interface Differences.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Drug-Device Combination Products 101: Identifying, Developing, and Evaluating Drug-Device Combination Products. Hybrid Meeting. Rockville, MD, May 10, 2023.

54. Feng K. *Acceptability of Using Alternative Pk Metrics from Systemic Pharmacokinetic (Pk) Data to Inform Regional Deposition for Orally Inhaled Drug Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 21, 2023.

55. Feng K. *ANDA Challenges Related to Vasoconstrictor Studies.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) Bioequivalence and Bioavailability Science Community (BEBAS) Community. Virtual Meeting, Sep. 28, 2023.

56. Feng K. *ANDA Challenges Related to Vasoconstrictor Studies.* Presentation at the SSmall Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

57. Flint J. *Best Practices for Comparative Use Human Factors Study Design, Execution, and Reporting.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Drug-Device Combination Products 101: Identifying, Developing, and Evaluating Drug-Device Combination Products. Hybrid Meeting. Rockville, MD, May 10, 2023.

58. Ganley W. *Determining the Role of In Silico Methods for OINDP Generic Biowaivers.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

59. Ghosh A. *General Approach to the Safety Review of Pediatric Excipients.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

60. Ghosh P, and Patel H. *General Guidances Related to Characterization-Based Bioequivalence Approaches for Topical Products.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

61. Ghosh P. *Characterization-Based Bioequivalence Approaches for Topical Products Part 1: Q3 Guidance.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

62. Ghosh P. *GDUFA Science and Research Collaborating with the FDA Research Program.* Presentation at the SPIE Photonics West: FDA Policies and Procedures: What Academic Investigators and Small Business Should Know. San Francisco, CA, Jan. 30, 2023.

63. Ghosh P. *Impact of GDUFA Regulatory Science and Research Program on Topical Product Availability.* Presentation at the Dermatology Innovation Webinar - The Science Behind Innovations in Topical Generic Drug Assessment: Opportunities and Challenges. Virtual Meeting, Sep. 19, 2023.

64. Ghosh P. *Role of Regulatory Science Research Topical Product Development.* Presentation at the Innovations in Dermatological Sciences Conference. Virtual Meeting, Sep. 28, 2023.

65. Ghosh P. *Visualizing and Quantifying Drugs Dermal Drug Development.* Presentation at the SPIE Photonics West: Visualizing and Quantifying Drug Distribution in Tissue. San Francisco, California, Jan. 28, 2023.

66. Giacomini K, and Tsakalozou E. *A Critical Overview of the Biological Effects of Excipients (Part I): Impact on Gastrointestinal Absorption.* Presentation at the AAPS Oral PBPK Webinar. Virtual Meeting, Mar. 21, 2023.

67. Gong Y. *Considerations for FEV1-based Comparative Clinical Endpoint or Pharmacodynamic Bioequivalence Studies for Orally Inhaled Drug Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

68. Grahek R. *Determination of Nitrite in Pharmaceutical Excipients: Air as Source for Higher Nitrite Levels.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, Maryland, Jun. 15, 2023.

69. Hartka K. *Pre-ANDA Program Support of Generic Drug-Device Combination Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Drug-Device Combination Products 101: Identifying, Developing, And Evaluating Drug-Device Combination Products. Hybrid Meeting. Rockville, MD, May 10, 2023.

70. Heflich R. *FDA/NCTR Activities: Ames Optimization Effort and In Vitro Alternatives.* Presentation at the FDA and the Health and Environmental Science Institute (HESI) Workshop on Research Roadmap Planning on Hazard and Risk Assessment of Nitrosamine Impurities in Drugs. Virtual Meeting, May 31, 2023.

71. Heflich R. *Nitrosamine Drug Impurities and Nitrosamine Drug Substance Related Impurities: Optimizing Mutagenicity Testing.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

72. Heflich R. *Research Being Conducted at NCTR/FDA on N-nitrosamine Impurities.* Presentation at the 2022 Association for Affordable Medicines (AAM): GRx + Biosims Conference. North Bethesda, MD, Nov. 07, 2022.

73. Heflich R. *Work being done at FDA/NCTR with HepaRG cells.* Presentation at the Health and Environmental Sciences Institute (HESI)- Genetic Toxicology Technical Committee (GTTC) Annual Meeting. Hybrid Meeting. Washington, DC, May 08, 2023.

74. Hochhaus G. *Dissolution Tests for OIDPs: Opportunities and Challenges.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

75. Holl M. *Materials for Aerosol Treatment of Disease: New Microscopy for Bioequivalence and Improving Therapeutic Index.* Presentation at the University of Alabama Cystic Fibrosis Research Center (CFRC). Virtual Meeting, Jan. 24, 2023.

76. Holtgrewe N. *Alternative Bioequivalence Approach Using Morphologically-Directed Raman Spectroscopy (MDRS) on Nasal Spray Suspensions.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 21, 2023.

77. Holtgrewe N. *Alternative In Vitro Bioequivalence Methods for Testing Generic Orally Inhaled Drug Products.* Presentation at the Fiscal Year (FY) 2023 Generic Drug Science and Research Initiatives Public Workshop. Hybrid Meeting. Silver Spring, MD, May. 12, 2023.

78. Hooker A. *A Population PK Based Model-Integrated BE Platform.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 28, 2022.

79. Hu M. *Dose Scale Analysis to Support Bioequivalence Assessment.* Presentation at the Small Business and Industry Assistance (SBIA) Webinar: A Deep Dive: FDA Draft Guidance on Statistical Approaches to Establishing Bioequivalence. Virtual Meeting, Mar. 14, 2023.

80. Hu M. *Use of Data Analytics Approaches to Support Regulatory Assessment - from FDA Perspective.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 28, 2022.

81. Iliopoulos F, Pence I, Ghosh P, Raney S, Luke M, and Evans E. *Stimulated Raman Scattering (SRS) Microscopy and Deep Learning: Novel Pharmacokinetic Approach for Evaluation of Topical Bioequivalence.* Presentation at the 2023 SPIE Photonics West. San Francisco, CA, Jan. 28, 2023.

82. Iliopoulos F. *SRS Microscopy and Deep Learning: Novel Approach for Evaluation of Topical Bioequivalence.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 18, 2022.

83. Jani R. *Establishing Bioequivalence Using Characterization Based Approaches for Topical Products - Challenges & Solutions.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development. Virtual Meeting, Nov. 03, 2022.

84. Jiang W. *Complex Generics Containing Nanomaterials: What's Next in the Pipeline?* Presentation at the American Association of Pharmaceutical Scientists (AAPS) - Chicagoland Pharmaceutical Discussion Group (CPDG). Chicago, IL, May 19, 2023.

85. Jiang W. *FDA Drug Topics: Understanding Generic Narrow Therapeutic Index Drugs.* Presentation at the FDA Division of Drug Information Continuing Education Webinar Series. Virtual Meeting, Oct. 25, 2022.

86. Kamal N. *Dermal Drug Delivery via Dissolvable Microneedles: Formulation Variables Affecting CQAs.* Presentation at the FDA Science Forum 2023. Virtual Meeting, Jun. 14, 2023.

87. Kamal N. *Formulation Variables Affecting CQAs of Dissolvable Microneedles.* Presentation at the AAPS 2023 PharmSci 360. Orlando, FL, Oct. 25, 2023.

88. Kamal N. *Identification of Formulation Variables Affecting the Performance of Dissolvable Microneedles.* Presentation at the Microneedle Conference 2023. Seattle, WA, May 16, 2023.

89. Kaviratna A. *General Considerations for the Quantitative Sameness Evaluation of a Proposed Generic Formulation.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

90. Keire D. *Mitigation Studies for Nitrosamines in Pharmaceutical Formulations.* Presentation at the Small Business and Industry Assistance (SBIA) - Generic Drugs Forum (GDF) 2023: Celebrating 10 Years of the GDF. Virtual Meeting, Apr. 13, 2023.

91. Kelchen M. *An Overview of the Current Product-Specific Guidances for Topical Products.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

92. Kelchen M. *General Considerations for the "No Significant Difference" Evaluation of a Proposed Generic Formulation.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

93. Kelly M. *REMOVE Utilizing Modelling Approaches to Support Regulatory Submission for Orally Inhaled Drug Products: Case Example.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) 2022: Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 27, 2022.

94. Kim E. *Best Practices for Submitting Formulation Assessment Requests and Avoiding Information Requests: Tips for Submitting a Proposed Formulation Table.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

95. Kim T. *Formulation Considerations for Selecting an Appropriate RLD or RS.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

96. Kourmatzis A. *Laser and Optical Diagnostics for Characterization of DPIs.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 21, 2023.

97. Kozak D. *Considerations for Post-Approval Changes to Complex Generic Drug Products.* Presentation at the 2022 Association for Affordable Medicines (AAM): GRx + Biosims Conference. North Bethesda, MD, Nov. 08, 2022.

98. Kozak D. *Development and Characterization of Generic Drug Products Containing Nanomaterials.* Presentation at the FDA NanoDay Symposium 2022. Virtual Meeting, Oct. 11, 2022.

99. Kruhlak N. *Using Structure-Activity Relationships to Inform Setting Acceptable Intakes for Nitrosamine Impurities.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

100. Kuehster L. *Stochastic and Deterministic Analysis of Reactivity Ratios in the Partially Reversible Copolymerization of Lactide and Glycolide.* Presentation at The American Institute of Chemical Engineers (AIChE) Annual Meeting. Phoenix, AZ, Nov. 13, 2022.

101. Kuzma B, Senemar S, and Stagni G. *A Microdialysis Approach to Assess Dermal Pharmacokinetics of Topical Dermatological Drug Product.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development. Virtual Meeting, Nov. 03, 2022.

102. Le C. *An Overview of the FDA Product-Specific Guidance (PSG) Program Under GDUFA III.* Presentation at the Small Business and Industry Assistance (SBIA) - Generic Drugs Forum (GDF) 2023: Celebrating 10 Years of the GDF. Virtual Meeting, Apr. 12, 2023.

103. Le Merdy M. *Ophthalmic Drug Products: Leveraging M&S Approaches to Perform Inter-Species Predictions and Support Drug Product Development and Approval.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 27, 2022.

104. Lee J. *In Silico Study of the Effect of Including Lactose Fines in Modeling Dry Powder Inhaler Performance.* Presentation at the FDA 2023 Scientific Computing Days. Virtual Meeting, Sep. 12, 2023.

105. Lee M. *Best Practices for ANDA Submission of Comparative Analyses for Drug-Device Combination Products & the ANDA User Interface Assessment Process.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Drug-Device Combination Products 101: Identifying, Developing, and Evaluating Drug-Device Combination Products. Hybrid Meeting. Rockville, MD, May 10, 2023.

106. Li X. *Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use - Guidance Implementation in Q1/Q2 Assessment.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

107. Li X. *Genotoxicity Assessment of Eight Nitrosamine Impurities using 2D and 3D HepaRG Cell Models.* Presentation at the 54th Annual Meeting of Environmental Mutagenesis and Genomics Society (EMGS). Chicago, IL, Sep. 09, 2023.

108. Lin C. *Cluster-Informed In Silico and In Vivo Regional Deposition Assessments.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 21, 2023.

109. Lionberger R. *Complex Generics 2022 Update.* Presentation at the 2022 Association for Affordable Medicines (AAM): GRx + Biosims Conference. North Bethesda, MD, Nov. 09, 2022.

110. Lionberger R. *Generic Competition for Inhalation Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

111. Lu D. *FDA Guidance - Control of Nitrosamines in Human Drugs.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for

Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

112. Lu X. *Novel In Vitro, Ex Vivo and In Vivo Assessment of Ophthalmic Semi-Solid Drug Products.* Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 27, 2023.

113. Lukacova V. *Application of Modeling and Simulation in Long-Acting Injectable Product Development.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 18, 2022.

114. Lukacova V. *Building Mechanistic IVIVC.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 28, 2022.

115. Lukacova V. *Current Status and Gaps in Mechanistic In-Silico Modeling for Clinical Translation and Performance.* Presentation at the American Association of Pharmaceutical Scientists (AAPS): Patient-Centric Design of Long-Acting Injectable Drug Products. Virtual Meeting, Oct. 10, 2022.

116. Luke M. *Development of Complex Generic Drugs in the United States.* Presentation at the 2022 NIFDS -DIA Conference : New Logics of High-Tech Drug Development and Quality Challenges. Seoul, Korea, Nov. 17, 2022.

117. Luke M. *FDA for the Dermatologist - The Basics About FDA and Advances in Science and Regulation of Topical Generic Drugs.* Presentation at the American Academy of Dermatology (AAD) Annual Meeting. New Orleans, LA, Mar. 18, 2023.

118. Luke M. *FDA Sponsored Drug Research Towards Generics for Dermatology.* Presentation at the Advancing Innovation in Dermatology 2023. New Orleans, LA, Mar. 16, 2023.

119. Luke M. *FDA Update: FDA and Dermatology DEIA.* Presentation at the 100th Annual Atlantic Derm Conference. Baltimore, MD, May 14, 2023.

120. Luke M. *Generic Drugs and Dermatology: Bioequivalence and Access Equity.* Presentation at the Noah Worcester Dermatological Society: 64th Annual Meeting. Napa, CA, May 06, 2023.

121. Luke M. *Innovation and Topical Generic Drug Science: A Case of Targeted and Planned Innovation.* Presentation at the Dermatology Innovation Webinar - The Science Behind Innovations in Topical Generic Drug Assessment: Opportunities and Challenges. Virtual Meeting, Sep. 19, 2023.

122. Luke M. *On Understanding the Clinical Relevance of "Formulation" for Topical Applied to the Skin.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development. Virtual Meeting, Nov. 03, 2022.

123. Mallick B. *Specificity and Discriminatory Challenges Leading to Limitation in Accurate Complete Identification and Quantification of Excipients in RLS Deformulation.* Presentation at the FFDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

124. Mannion M. *FDA Responses to Questions on Q1/Q2 Sameness.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

125. Mannion M. *Requirements and Recommendations Related to Inactive Ingredients.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

126. Mohammed Y. *Development of Methods for Evaluation of Formulation Differences and their Impact on Therapeutic Equivalence: Broadening the Therapeutic Scope.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development. Virtual Meeting, Nov. 03, 2022.

127. Moser J. *Distilling a Complex Problem into Quantitative Tools and Approaches to Address N-nitrosamine Formation Risk in Drug Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

128. Mousa Y. *Evaluation of Dissolution Profile Similarity for Bioequivalence Assessment.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 28, 2022.

129. Murthy S. *Influence of Progressive Change in the Degree of Saturation of API on the Performance of Topical Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development. Virtual Meeting, Nov. 03, 2022.

130. Newman B. *Challenges & Considerations for the Transition to Low Global Warming Potential (LGWP) Propellants with Metered Dose Inhalers.* Presentation at the Next Gen Inhalation Delivery Summit. Boston, MA, Jun. 21, 2023.

131. Newman B. *Design Considerations for Alternative Bioequivalence Approaches for Generic Orally Inhaled Drug Products.* Presentation at the Respiratory Drug Delivery (RDD) Europe 2023. Antibes (Nice), France, May 05, 2023.

132. Newman B. *Designing Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies - Does One Approach Fit All for Generic Orally Inhaled Drug Products?* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

133. Nigam S. *Overview of Pre-ANDA Meetings Under GDUFA III.* Presentation at the Small Business and Industry Assistance (SBIA) - Generic Drugs Forum (GDF) 2023: Celebrating 10 Years of the GDF. Virtual Meeting, Apr. 12, 2023.

134. Nudelman R. *Position Papers for Classes of NDSRIs.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

135. Nudelman R. *Proposed Methods to Set Limits for Nitrosamine Drug Substance Related Impurities (NDSRIs).* Presentation at the Fiscal Year (FY) 2023 Generic Drug Science and Research Initiatives Public Workshop. Hybrid Meeting. Silver Spring, MD, May 11, 2023.

136. Pang E. *PSG Recommendations for Risk-based Comparative Immunogenicity and Impurity Profile Assessment.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 14, 2023.

137. Patil S. *Challenges and Learnings with Device Development and Comparative User Interface Assessment for DDCP.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG)Drug-Device Combination Products 101: Identifying, Developing, and Evaluating Drug-Device Combination Products. Hybrid Meeting. Rockville, MD, May 10, 2023.

138. Phung T. *Pathways for Receiving FDA's Feedback on Formulations.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

139. Ponting D. *Why Do Nitrosamine Potencies Vary So Widely? Mechanistic Rationales for the Effects of Structural Features on Activity.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

140. Qin B. *Amphotericin B Liposome: Revisions of the Product Specific Guidance.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

141. Ramezanli T. *A Case Study to Evaluate the Performance of Dermal Open Flow Microperfusion And Dermal Microdialysis for Assessing the Cutaneous Pharmacokinetics of Topical Lidocaine And Prilocaine Cream.* Presentation at the Innovations in Dermatological Sciences Conference. Virtual Meeting, Sep. 29, 2023.

142. Ramezanli T. *Characterizing In Vivo Cutaneous Pharmacokinetics of Topical Lidocaine Prilocaine Cream using Dermal Open Flow Microperfusion and Dermal Microdialysis.* Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 26, 2023.

143. Ramezanli T. *Cutaneous Pharmacokinetics-Based Techniques: Translating Scientific Advances to Regulatory Methods.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development. Virtual Meeting, Nov. 03, 2022.

144. Ramezanli T. *Novel Approaches for Evaluating Bioavailability and Bioequivalence (BE) of Topical Drug Products.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 18, 2022.

145. Ramezanli T. *Translating Science to Regulatory Tools: Novel Approaches for Characterizing and Evaluating the Performance of Topical Drug Products.* Presentation at the Dermatology Innovation Webinar - The Science Behind Innovations in Topical Generic Drug Assessment: Opportunities and Challenges. Virtual Meeting, Sep. 19, 2023.

146. Raney S. *A Research Strategy to Develop Efficient BE Approaches for Complex Generic Topical Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development. Virtual Meeting, Nov. 03, 2022.

147. Raney S. *GDUFA Research Program: Research Priorities to Support Generic Drug Development.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval. Virtual Meeting, Sep. 14, 2023.

148. Raney S. *Generic Drug Science & Research Priorities for Fiscal Year (FY) 2023.* Presentation at the FDA Broad Agency Announcement Day 2022. Virtual Meeting, Dec. 06, 2022.

149. Raney S. *Revision to U.S. Pharmacopeia General Chapter <1724> Semisolid Drug Products – Performance Tests In Vitro Permeation Test (IVPT).* Presentation at the American Association of Pharmaceutical Scientists Topical and Transdermal Community Roundtable Discussion. Virtual Meeting, Dec. 09, 2022.

150. Raney S. *Scientific and Regulatory Advances for Complex Generic Topical Products.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 17, 2022.

151. Raney S. *Scientific and Regulatory Considerations for Generic Drug Products.* Presentation at the University of Michigan. Virtual Meeting, Nov. 10, 2022.

152. Ren K. *Challenges and General Considerations of Conducting Pharmacodynamic Equivalence Studies for Albuterol Sulfate Metered Dose Inhalers.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

153. Rostami A. *Improving Model Reusability via the Concept of Model Master File: What the Literature Data Tell Us.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 28, 2022.

154. Sachdeva S. *Effect of Formulation Differences on Critical Quality Attributes and Performance of the Complex Topical Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development. Virtual Meeting, Nov. 03, 2022.

155. Sarago C. *GDUFA III Product-Specific Guidance (PSG) Teleconferences.* Presentation at the Small Business and Industry Assistance (SBIA) Webinar - A Deep Dive: GDUFA III Scientific Meetings. Virtual Meeting, May 15, 2023.

156. Shakleya D. *Development and Validation of Ion Chromatography Methods for the Evaluation of Nitrosamine Precursors (Nitrite, Nitrate, and Dimethylamine).* Presentation at the American Chemical Society (ACS) Spring 2023: Crossroads of Chemistry. Indianapolis, IN, Mar. 26, 2023.

157. Shakleya D. *Effectiveness of Antioxidants in Selected Model Drugs: Mitigation Strategy and Impact of Reformulation in their Stability.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

158. Shakleya D. *Nitrosamine Additives Mitigation Studies.* Presentation at the Fiscal Year (FY) 2023 Generic Drug Science and Research Initiatives Public Workshop. Hybrid Meeting. Silver Spring, MD, May 11, 2023.

159. Shur J. *Understanding Time-Evolved Changed in Morphology of Pharmaceutical Aerosol Systems.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, Maryland, Apr. 21, 2023.

160. Sinner F. *Continuous Skin Sampling Methods for the Assessment of Cutaneous PK-Based Bioequivalence.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Formulation Characterization and Cutaneous Pharmacokinetics to Facilitate Generic Topical Product Development. Virtual Meeting, Nov. 03, 2022.

161. Smith W. *Impact of Particle Flocculation on Particle Size Determination and Implications on Dissolution and Bioavailability of Injectable Suspensions.* Presentation at the International Foundation Process Analytical Chemistry (IFPAC) 2023. North Bethesda, MD, Jun. 04, 2023.

162. Smith W. *Phytonadione – Self-Assembled System & Thermodynamics Systems.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

163. Soukup S. *Challenges and Recommendations in Comparative Clinical Endpoint Bioequivalence Studies in Dry Powder Inhaler Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

164. Stass H. *Biopharmaceutical Characterization of Orally Inhaled Drug Products Using Scintigraphy in Combination with Charcoal Block -Case Study Ciprofloxacin Dry Powder for Inhalation.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

165. Sun W. *Bioequivalence for Oral Locally Acting Gastrointestinal Drug Products.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 14, 2023.

166. Svensson M. *Which Test and Handling Factors Affect the MDI Performance?* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

167. Teasdale A. *Hydrochlorothiazide – a Twist in the Tail.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

168. Trampuz M. *Assessment of a Diverse Array of Nitrite Scavengers in Solution and Solid State: A Study of Inhibitory Effect on the Formation of Alkyl-Aryl and Dialkyl N-Nitrosamine Derivatives.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

169. Tsakalozou E. *Mechanistic Modeling and Simulation Approaches for Performance Prediction of Locally Acting Complex Drug Products.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 18, 2022.

170. Tsakalozou E. *Physiologically-Based Pharmacokinetic Modeling to Support Bioequivalence and Drug Approval.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 18, 2022.

171. Tsong Y. *Statistical Experience and Challenges in Assessing Similarity of Dissolution Profiles, Particle Size Distributions and API Sameness.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 28, 2022.

172. Usmani O. *Total and Regional Lung Delivery of Salbutamol in Subjects with Idiopathic Pulmonary Fibrosis (IPF).* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

173. Uwemedimo I, and Lauritsen K. *Definition of a Combination Product and the Complementary and Collaborative Roles of FDA's Office of Combination Products & CDER's Product Jurisdiction Office Have on Classifying Products as Drugs, Devices, or Drug-Device Combination Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG)Drug-Device Combination Products 101: Identifying, Developing, and Evaluating Drug-Device Combination Products. Hybrid Meeting. Rockville, MD, May 10, 2023.

174. Van Gessel S. *Reducing Nitrosamines Without the Use of Scavengers: The Critical Role of Excipients.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Rockville, Maryland, Jun. 15, 2023.

175. Verthelyi D. *Current FDA Thinking on the use of Non-Clinical Tools in Immunogenicity Risk Assessments: Possibilities and Challenges.* Presentation at the 14th Open Scientific EIP Symposium on Immunogenicity of Biopharmaceuticals.. Lisbon, Portugal, Apr. 27, 2023.

176. Verthelyi D. *Innate Immune Response Modulating Impurities Testing for Generics and Biosimilars: Where We Are and What We Are Missing.* Presentation at the 19th Annual PEGS BOSTON Summit – the Essential Protein and Antibody Engineering. Boston, MA, May 15, 2023.

177. Verthelyi D. *Tools to Assess Immunogenicity Risk and New Computational Methods.* Presentation at the 17th Workshops on Recent Issues in Bioanalysis (WRIB). Orlando, FL, Jun. 20, 2023.

178. Walenga R. *Complex Nasal Suspensions: Utilization of In Silico Studies to Support Development and Approval.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

179. Walenga R. *Model Purpose and Selection for Supporting Development and Approval of Generic Locally Acting Orally Inhaled Drug Products in the United States.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

180. Walenga R. *Modeling and Simulation to Support Development and Approval of Generic Orally Inhaled Drug Products.* Presentation at the Society for Pharmaceutical Dissolution Science (SPDS): In Vitro and In Silico Predictions of Orally Inhaled Drug Product In Vivo Performance. Virtual Meeting, Sep. 15, 2023.

181. Walenga R. *Predicting Regional Deposition, Local and Systemic Pharmacokinetics of Orally Inhaled Drug Products.* Presentation at the Society for Pharmaceutical Dissolution Science USA (SPDS-US) - Webinar. Virtual Meeting, Sep. 15, 2023.

182. Walenga R. *Utilizing In Vitro and In Silico Methods to Accelerate Product Development for Generic Nasal Drug Products.* Presentation at the Novel Nasal Formulation and Delivery Summit 2023. San Diego, CA, May 18, 2023.

183. Wang Y. *Considerations for the Qualitative Sameness Evaluation of a Proposed Generic Formulation.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.

184. Wang Y. *Scientific and Regulatory Considerations on In Vitro Release Testing (IVRT) and In Vitro In Vivo Correlation (IVIVC) for Complex Long-Acting Drug Suspensions.* Presentation at the IQ Webinar: Scientific and Regulatory Considerations for Long-acting Injectable Suspensions. Virtual Meeting, Jul. 21, 2023.

185. Ward J. *Implementing a Clinical Endpoint BE Study for Wixela Inhub: An Industry Viewpoint.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, MD, Apr. 20, 2023.

186. Wu F, and Tsakalozou E. *A Critical Overview of the Biological Effects of Excipients.* Presentation at the Excipient World Conference & Expo 2023. National Harbor, MD, May 02, 2023.

187. Wu F. *Assessing Food Impact on Bioequivalence Using Physiologically-Based Pharmacokinetic Modeling.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 18, 2022.

188. Wu F. *How Might Excipients Impact Bioequivalence Assessments of Human Generic Drug Products.* Presentation at the 2023 March AAPS Webinar. Virtual Meeting, Mar. 23, 2023.

189. Wu F. *OGD Perspectives on PBBM Applications for Generics.* Presentation at the FDA/M-CERSI Physiologically Based Biopharmaceutics Modeling Workshop. Rockville, MD, Aug. 31, 2023.

190. Wu F. *Physiologically Based Pharmacokinetic (PBPK) Absorption Modeling to Evaluate the Impact of Excipients on Bioequivalence of BCS Class III Drug Products.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

191. Wu F. *Using PBPK Model to Support Risk Assessment for Oral Products, from a Regulatory Perspective.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 27, 2022.

192. Wu F. *Using PBPK Model to Support Risk Assessment for Oral Products.* Presentation at the Peking University Third Hospital 2023. Virtual Meeting, Jan. 13, 2023.

193. Wu F. *Using Physiologically Based Pharmacokinetic Absorption Modeling for Bioequivalence Evaluation in Adult and Pediatric Populations.* Presentation at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) 2023 Webinar. Virtual Meeting, Apr. 27, 2023.

194. Xu X. *Challenges and Opportunities of Continuous Manufacturing inf Nanomaterials.* Presentation at the National Nanotechnology Initiative Workshop. Hybrid Meeting. Washington, DC, Mar. 23, 2023.

195. Xu X. *Future of Continuous Manufacturing in Drug Products Containing Nanomaterials.* Presentation at the FDA NanoDay Symposium 2022. Virtual Meeting, Oct. 11, 2022.

196. Xu X. *Identify Research Needs and PSG Development for Complex Products.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval. Virtual Meeting, Sep. 13, 2023.

197. Xu X. *In Vitro Release Test for Complex Drug Product: What is Your Perspective?* Presentation at the American Association of Pharmaceutical Scientists (AAPS) - Chicagoland Pharmaceutical Discussion Group (CPDG). Chicago, IL, May 19, 2023.

198. Xu X. *One Size Does Not Fit All: Challenges of Particle Size Measurement in Pharmaceutical Applications.* Presentation at the Bureau International des Poids et Mesures (BIPM): CCQM Workshop on Particle Metrology. Virtual Meeting, Oct. 26, 2022.

199. Xu X. *Opportunities in Continuous Manufacturing of Nanomaterials.* Presentation at the Controlled Release Society (CRS) 2023 Annual Meeting and Exposition. Las Vegas, NV, Jul. 24, 2023.

200. Xu X. *Opportunities in Continuous Manufacturing of Nanomaterials.* Presentation at the Research Center Pharmaceutical Engineering (RCPE): Accelerating Access to Medicines Workshop. Washington, DC, Mar. 28, 2023.

201. Xu X. *Roundtable Discussion: Dissolution Testing of Nanoparticles.* Presentation at the SelectScience Webinar. Virtual Meeting, Jun. 07, 2023.

202. Xu. *Complex Equilibria and Complex Drug Products: Role of Fundamentals in Advancing Regulatory Science.* Presentation at the University of Connecticut. Virtual Meeting, Nov. 28, 2022.

203. Yang J. *Performance Characteristics of Mass Spectrometry Based Methods for Quantitation of Nitrosamines: Insight from an Inter-laboratory Study.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

204. Yang K, Abdhullah A, Islam R, Dieke N, Sommers C, Rodriguez J, Zhang D, Kozak D, and Keire D. *LC-HRMS-based Multi-Attribute Method for Oligonucleotides (MAMO).* Presentation at the American Society for Mass Spectrometry (ASMS) - 71st Conference on Mass Spectrometry and Allied Topics. Houston, Texas, Jun. 08, 2023.

205. Yang K. *LC-HRMS-based Multi-Attribute Method for Oligonucleotides (MAMO) to Resolve Complexities.* Presentation at the 3rd Chinese American Society Mass Spectrometry Annual Conference. Virtual Meeting, Aug. 28, 2023.

206. Yee S. *Effects of Antioxidants in Drugs Products on Intestinal Drug Transporters.* Presentation at the Fiscal Year (FY) 2023 Generic Drug Science and Research Initiatives Public Workshop. Hybrid Meeting. Silver Spring, MD, May 11, 2023.

207. Yee, S. *Effects of Antioxidants in Drugs Products on Intestinal Drug Transporters.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics. Hybrid Meeting. Rockville, MD, Jun. 15, 2023.

208. Zeng X. *The Use of In Vitro Characterization Techniques to Support the Demonstration of Bioequivalence of Generic Orally Inhaled Products Designed to Be Bioequivalent to Their Reference Listed Drugs.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products. Rockville, Maryland, Apr. 21, 2023.

209. Zhang F. *Melt-Extruded Dexamethasone Ophthalmic Implants: Process, Structure and In Vitro Drug Release.* Presentation at the 4th Annual Formulation and Drug Delivery USA Conference. San Diego, CA, Oct. 11, 2022.

210. Zhang L, Tampal N, and Kim M. *Navigating the First ICH Generic Drug Draft Guideline "M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms".* Presentation at the Small Business and Industry Assistance (SBIA) Webinar- Navigating the First ICH Generic Drug Draft Guideline “M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms”. Virtual Meeting, May 02, 2023.

211. Zhang L. *FDA Scientific Efforts on Investigating Excipient-Drug Interactions.* Presentation at the Marbach Castle Drug-Drug Interaction Workshop Series (DDI) 2023. Marbach Castle, Germany, Jun. 06, 2023.

212. Zhang L. *FDA-EMA Parallel Scientific Advice Pilot Program for Complex Generic/Hybrid Drug Products.* Presentation at the Small Business and Industry Assistance (SBIA) - Advancing Generic Drug Development: Translating Science to Approval. Virtual Meeting, Sep. 14, 2023.

213. Zhang L. *GDUFA III Teleconferences and Meetings.* Presentation at the Generics + Biosimilars Conference 2022. North Bethesda, MD, Nov. 07, 2022.

214. Zhang L. *Regulatory Science to Support Global Harmonization for Establishing BE for Generic Oral Products.* Presentation at the FY2023 Generic Drug Science and Research Initiatives Public Workshop. Virtual Meeting, May 11, 2023.

215. Zhang L. *Introduction to GDUFA III Meetings.* Presentation at the Small Business and Industry Assistance (SBIA) Webinar - A Deep Dive: GDUFA III Scientific Meetings. Virtual Meeting, May 15, 2023.

216. Zhang Q. *In Vitro Bioequivalence Approaches for Injectable Drug Substance Suspension Products: Medroxyprogesterone Acetate* . Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval. Virtual Meeting, Sep. 13, 2023.

217. Zhang Q. *In Vitro Approaches for Injectable Suspension Products: Medroxyprogesterone Acetate & Triamcinolone Acetate.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

218. Zhao L. *Applying Modeling & Simulation to Support Drug Lifecycle Management.* Presentation at the AAPS Webinar. Virtual Meeting, Aug. 15, 2023.

219. Zhao L. *Generating Model-integrated Evidence for Developing and Approving Complex Generic LAI Products.* Presentation at the American Conference on Pharmacometrics (ACoP) 2022. Aurora, CO, Nov. 02, 2022.

220. Zhao L. *Introduction: Statistical Approaches to establishing Bioequivalence.* Presentation at the Small Business and Industry Assistance (SBIA) Webinar: A Deep Dive: FDA Draft Guidance on Statistical Approaches to Establishing Bioequivalence. Virtual Meeting, Mar. 14, 2023.

221. Zhao L. *Mechanistic Drug Delivery Models.* Presentation at the 1st Academic Committee Meeting of Joint R&D Center. Beijing, China, Dec. 31, 2022.

222. Zhao L. *Mechanistic Drug Delivery Models.* Presentation at the 2022 Annual Meeting for Professional Committee of Pharmacometrics, Chinese Pharmacological Society. Virtual Meeting, Nov. 25, 2022.

223. Zhao L. *Mechanistic Drug Delivery Models.* Presentation at the Drexel University, Biomedical Seminar Series. Virtual Meeting, Feb. 08, 2023.

224. Zhao L. *Mechanistic Drug Delivery Models.* Presentation at the Pharmacometrics Youth Forum Shanghai 2022. Virtual Meeting, Oct. 09, 2022.

225. Zhao L. *Model-Integrated Evidence (MIE) Industry Meeting Pilot Between FDA and Generic Drug Applicants.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 14, 2023.

226. Zhao L. *Potential Types of Model Master Files.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Best Practices for Utilizing Modeling Approaches to Support Generic Product Development. Virtual Meeting, Oct. 28, 2022.

227. Zidan A. *Advancements in the in vitro Characterization Methodologies for Alternative BE Approaches of Locally Acting Complex Drug Products.* Presentation at the American Association of Pharmaceutical Scientists (AAPS) 2022. Boston, MA, Oct. 18, 2022.

228. Zidan A. *How Research Supports Product-Specific Guidances for Topical Products.* Presentation at the Small Business and Industry Assistance (SBIA) Workshop: Advancing Generic Drug Development: Translating Science to Approval 2023. Virtual Meeting, Sep. 13, 2023.

229. Zuk S. *Inactive Ingredient Database (IID) Overview.* Presentation at the FDA and the Center for Research on Complex Generics (CRCG) Workshop on Excipients and Formulation Assessments of Complex Generic Products: Best Practices and Lessons Learned. Virtual Meeting, Dec. 06, 2022.