Presentations Relating to GDUFA Research in Fiscal Year 2018

1. Amidon, G. *In Vivo Predictive Dissolution (iPD) to Advance Oral Drug Product Development*. Presentation at Biorelevant? Symposium. Copenhagen, Denmark, Dec. 30, 2017.
2. Andre, K. *Pre-ANDA Program*. Presentation at Association for Accessible Medicines (AAM) Fall Tech Conference. North Bethesda, MD, Nov. 8, 2017.
3. Andre, K. *Using the Eportal for Pre-ANDA Meeting Requests*. Presentation at Generic Drug Forum (GDF) 2018. Silver Spring, MD, Apr. 11, 2018.
4. Andre, K. *Pre-ANDA Meeting Process*. Presentation at Generic Drug Forum (GDF) 2018. Silver Spring, MD, Apr. 11, 2018.
5. Andre, K. *Complex Products - GDUFA II Pre-ANDA Program*. Presentation at Grx+Biosims 2018 (AAM). Baltimore, MD, Sept. 7, 2018.
6. Andre, K. *Pre-ANDA Logistics and Best Practices*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.
7. Babiskin, A. *Physiologically-Based Absorption Modeling and Simulation Used in Assessing Bioequivalence for Ophthalmic Products*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.
8. Bellantone, R. *Pulsatile Microdialysis of Suspension and Emulsion Products*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.
9. Benson, H. *Correlation of Physicochemical Characteristics and In Vitro Permeation Test (IVPT) Results for Acyclovir Topical Products*. Presentation at Drug Delivery Australia. Wollongong, Australia, Oct. 23, 2017.
10. Bunge, A. *Improved Stratum Corneum Sampling In Vivo Delivers Obvious Value for Topical Bioequivalence Assessment*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access. White Oak, MD, Oct. 20, 2017.
11. Burgess, D. *In Vitro Drug Release from Complex Parenterals and Development of IVIVCs*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.
12. Byron, P. *Clinically Relevant In Vitro Testing of Oral Inhalation Products Using Realistic Mouth-Throat Models*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.
13. Choi, J., LeBlanc, L. J., Choi, S., Haghighi, B., Hoffman, E. A., and Lin, C.-L. *Cluster-Guided Imaging-Based CFD Analysis of Airflow and Particle Deposition in Asthmatic Human Lungs*. Presentation at APS DFD. Denver, CO, Nov. 20, 2017.
14. Choi, J., LeBlanc, L. J., Choi, S., Haghighi, B., Hoffman, E. A., and Lin, C.-L. *Characteristcs of Inhaled Particle Deposition in the Lungs of Imaging-Based Asthma Clusters: A Numerical Study*. Presentation at ATS Preconference Current Practive and Future Development in Aerosol Medicine. San Diego, CA, May 19, 2018.
15. Conti, D. *Current Product-Specific Guidance's and Common Questions in Pre-ANDA Communications*. Presentation at Complex Generic Drug Product

Development Workshop. Silver Spring, MD, Sept. 13, 2018.

16. Dahmane, E., Gobburu, J., and Ivaturi, V. *Pharmacometric Approach to Define Narrow Therapeutic Index (NTI) Drugs & Evaluate Bioequivalence (BE) Criteria for NTI Drugs*. Presentation at Leveraging Quantitative Methods and Modeling to Modernize Generic Drug. White Oak, MD, Oct. 2, 2017.
17. Dandamudi, S. *In Vitro Bioequivalence Data for a Topical Product: Bioequivalence Review Perspective*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access. White Oak, MD, Oct. 20, 2017.
18. Delvadia, R. *GDUFA Regulatory Science Initiatives for Generic Orally Inhaled and Nasal Drug Products*. Presentation at Public Workshop: New Insights from Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products. Silver Spring, MD, Jan. 9, 2018.
19. Dutcher, S. *Use of Regulatory Science Research to Support Post-Marketing Surveillance of Generic Drug Products*. Presentation at Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review. White Oak, MD, Oct. 3, 2017.
20. Fan, J. *Potential Impact of Gastric Ph on Generic Drug Bioequivalence Evaluation*. Presentation at In Vivo/Formulation Predictive Dissolution Conference 2018. Lake Tahoe, NV, Mar. 6, 2018.
21. Fang, L. *Leveraging Quantitative Methods in Reviewing Complex/Locally Acting Products*. Presentation at Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review. White Oak, MD, Oct. 2, 2017.
22. Fang, L. *Marriage Between Quantitative Approaches and Regulatory Science: A Reality Check on Where We Are*. Presentation at American Conference on Pharmacometrics. Fort Lauderdale, FL, Oct. 17, 2017.
23. Fang, L. *Is Bioequivalence Established in Adults Relevant for Pediatrics?* Presentation at American Association of Pharmaceutical Scientists Annual Meeting Workshop: Dermatological Drug Products: Developmental & Regulatory Considerations. San Diego, CA, Nov. 12, 2017.
24. Ghosh, P. *Understanding the Complexity of Topical (Dermatological) Semisolids*. Presentation at NIPTE Continuous Manufacturing and Development of Complex Generics. Brooklyn, NY, Aug. 24, 2018.
25. Ghosh, P. *Product Development Considerations for Topical Products*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 13, 2018.
26. Giacomini, K. *The Effects of Excipients on Intestinal Drug Transporters*. Presentation at ACCP Annual Meeting. Bethesda, MD, Sept. 22, 2018.
27. Guo, C. *Analytical Method Development for Ingredient-Specific Particle Sizing of Nasal Spray Suspensions*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.
28. Guy, R. H. *Improved Stratum Corneum Sampling In Vivo Delivers Obvious Value for Topical Bioequivalence Assessment*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access. White Oak,

MD, Oct. 20, 2017.

29. Guy, R. H. *Measuring Drug Concentration in the Skin In Vivo: Techniques and Challenges*. Presentation at American Association of Pharmaceutical Scientists Annual Meeting Workshop: Dermatological Drug Products: Developmental & Regulatory Considerations. San Diego, CA, Nov. 12, 2017.
30. Hindle, M. *Comparing Nasal Suspension Products Using Realistic In Vitro Test Methods*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.
31. Hochhaus, G. *Development of an Optimized Dissolution Test System for OINDPs*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.
32. Hooker, A. *Model-Based Approaches as Guidance to Bioequivalence Decision Making: Design and Analysis Considerations*. Presentation at Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review. White Oak, MD, Oct. 2, 2017.
33. Hooker, A. C. *Improved Model-Based Bioequivalence Strategies*. Presentation at American Conference on Pharmacometrics. Fort Lauderdale, FL, Oct. 17, 2017.
34. Hu, M. *Prediction of the First ANDA Submission for NCEs Utilizing Machine Learning Methodology*. Presentation at Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review. White Oak, MD, Oct. 3, 2017.
35. Hu, M. *Predictive Analysis of First ANDA Submission for NCEs Based on Machine Learning Methodology*. Presentation at Drug Information Association (DIA) Annual Meeting. Boston, MA, June 24, 2018.
36. Hu, M. *Equivalence Testing of Complex Particle Size Distribution Profiles Based on Earth Mover's Distance*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.
37. Hu, M. *Big Data Toolsets to Pharmacometrics: Application of Machine Learning for Time-to-Event Analysis*. Presentation at American Conference of Pharmacometrics 9. San Diego, CA, Oct. 8, 2018.
38. Jiang, J. *Introduction to Complex Products and FDA Considerations*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.
39. Jiang, X. *Session 2: Novel Analytical Tools for Characterization of Nasal Suspensions*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.
40. Jiang, J. *An Overview of Challenges and Opportunities in the Development of Complex Generic Drug Products*. Presentation at DIA Webinar. Silver Spring, MD, Mar. 5, 2018.
41. Jiang, W. *Excipients in Parenteral Drug Products*. Presentation at Forum of Complex Injectable Product Development. Zhuhai, China, Mar. 14, 2018.
42. Jiang, W. *Summary of 2nd GBHI Workshop Session IV: Exclusion of Pharmacokinetic Data Is Bioequivalence Assessment*. Presentation at GBHI Conference. Amsterdam, Netherlands, Apr. 12, 2018.
43. Jiang, W. *US FDA Perspectives for Bioequivalence (BE) Evaluation of Liposome Drug Products*. Presentation at GBHI Conference. Amsterdam, Netherlands, Apr. 13,

2018.

44. Jiang, J. *Challenges and Opportunities for Innovation in Complex Generic Drug Product Development*. Presentation at Controlled Release Society (CRS) Annual Meeting. New York, NY, July 22, 2018.
45. Jiang, W. *In Vivo Relevance of Dissolution*. Presentation at 58th Annual Land O'Lakes Pharmaceutical Analysis Conference. Madison, WI, Aug. 7, 2018.
46. Jiang, J. *FDA Perspective: FDA Guidance Document and Current Thinking on ANDAs for Certain Highly Purified Synthetic Peptide*. Presentation at Canadian Society for Pharmaceutical Sciences (CSPS) and Health Canada Joint Workshop on Complex Formulations. Ottawa, CN, Sept. 10, 2018.
47. Jiang, W. *Regulatory Research in Nanomedicine Drug Products*. Presentation at AAPS Annual Guidance Forum. Rockville, MD, Sept. 11, 2018.
48. Kharasch, E., Russell, D., Shelden, M., Lenze, E., Miller, J., Blood, J., Kraus, K., Schweiger, J., A., S., and Rhea, M. *Bioequivalence and Clinical Effects of Generic and Brand Bupropion*. Presentation At. Oct. 12, 2017.
49. Kharasch, E. D. *Bioequivalence and Clinical Implications of Generic and Brand Bupropion*. Presentation at ACCP Annual Meeting. Bethesda, MD, Sept. 23, 2018.
50. Kinam, P. *Demonstrating Equivalence of Generic Complex Drug Substances and Formulations: Advances in Characterization and In Vitro Testing*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.
51. Kozak, D. *Introduction: Novel IVRT for Complex Formulations*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.
52. Kozak, D. *In Vitro Bioequivalence Testing for Topical Ophthalmic Suspension Products*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.
53. Lee, S. C. *Establishing Bioequivalence for Generic Oral Modified-Release Products: Regulatory Considerations and Utility of In Vivo Predictive Dissolution*. Presentation at In Vivo/Formulation Predictive Dissolution Conference 2018. Lake Tahoe, NV, Mar. 9, 2018.
54. Li, M. *Batch-to-Batch Pharmacokinetic Variability of Orally Inhaled Drug Products*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 13, 2018.
55. Zou, L. *Interactions of Azo Dyes Commonly Used in Oral Drug Products with the Organic Anion Transporting Polypeptide 2b1 (OATP2B1) and Human Gut Bacteria*. Presentation at ASCPT Annual Meeting. Orlando, FL, Mar. 22, 2018.
56. Lionberger, R. *Using Quantitative Methods and Modeling to Transform Generic Drug Development and Review*. Presentation at Lever- aging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review. White Oak, MD, Oct. 3, 2017.
57. Lionberger, R. *GDUFA Regulatory Science Research and the Future of Generic Drugs*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers

to Development and Improving Patient Access. White Oak, MD, Oct. 20, 2017.

58. Lionberger, R. *GDUFA II Pre-ANDA Program Meetings for Complex Products*. Presentation at Association for Accessible Medicines (AAM) Fall Tech Conference. North Bethesda, MD, Nov. 7, 2017.
59. Lionberger, R. *New Tools for Generic OIDPs to Maximize Prospects of FDA Approval*. Presentation at RDD 2018. Tuscon, AZ, Apr. 22, 2018.
60. Lionberger, R. *Bioequivalence and Complex Generics: How to Get Pre-Submission Advice*. Presentation at Drug Information Association (DIA) 2018 Global Annual Meeting. Boston, MA, June 24, 2018.
61. Lionberger, R. *What's Important to Consider When Developing a Complex Drug*. Presentation at Grx+Biosims 2018 (AAM). Baltimore, MD, Sept. 5, 2018.
62. Lionberger, R. *Closing Remarks*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 13, 2018.
63. Lionberger, R. *Can Clinical Pharmacology Break Down Barriers to Generic Substitution?* Presentation at ACCP Annual Meeting. Bethesda, MD, Sept. 24, 2018.
64. Luke, M. *Overcoming Barriers and Improving Patient Access to Topical Dermatological Drugs*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access. White Oak, MD, Oct. 20, 2017.
65. Luke, M. *Clinical Development of a Generic Topical Dermatological Drug Product*. Presentation at American Association of Pharmaceutical Scientists Annual Meeting Workshop: Dermatological Drug Products: Developmental & Regulatory Considerations. San Diego, CA, Nov. 12, 2017.
66. Luke, M. *Session 3: Realistic Models for Prediction of Regional Drug Deposition from Orally Inhaled and Nasal Drug Products (OINDPs)*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.
67. Luke, M. *Drug Compounding and the Dermatologist*. Presentation at AAD 2018. San Diego, CA, Feb. 19, 2018.
68. Luke, M. *Implications of Skin Anatomy, Skin (Patho-)Physiology, and Product Physico-Chemistry on FDA Regulatory Approach for Generic Dermatologic Products*. Presentation at 30th Anniversary Perspectives in Percutaneous Penetration Conference. LaGrandeMotte, France, Apr. 5, 2018.
69. Luke, M. *Bioequivalence of Transdermal Delivery Systems-Scientific Merits of the U.S. Approach*. Presentation at GBHI Conference. Amsterdam, Netherlands, Apr. 13, 2018.
70. Luke, M. Presentation at Johns Hopkins MD-PhD Program. Baltimore, MD, June 1, 2018.
71. Luke, M. *Biomaterials as Pertains to Drug Products, Including Generic Drug Products with Biomaterial Components*. Presentation at BEMA Summer 2018 Meeting. Woods Hole, MA, June 28, 2018.
72. Manna, S. *Liposomes: Physicochemical Characterization and In Vitro Drug Release Testing*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.

73. Murthy, S. N. *Characterizing the Critical Quality Attributes and In Vitro Bioavailability of Acyclovir and Metronidazole Topical Products*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access. White Oak, MD, Oct. 20, 2017.
74. Murthy, S. N. *Advanced Characterization Approaches for Topical Formulations*. Presentation at American Association of Pharmaceutical Scientists Annual Meeting. San Diego, CA, Nov. 15, 2017.
75. Murthy, S. N. *Microstructural Characterization and In Vitro Permeation Testing of Topical Products*. Presentation at Annual Transdermal & Intradermal Drug Delivery Systems. Philadelphia, PA, Sept. 7, 2018.
76. Nivorozhkin, A. *Liposomal Formulations of Amphotericin B*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.
77. O'Shaughnessy, P., Altmaier, R., Walenga, R., and Lin, C.-L. *Verifying the Hygroscopic Particle Growth Model During the Time Relevant to Lung Inspiration*. Presentation at 10th International Aerosol Conference. St. Louis, MO, Sept. 3, 2018.
78. Pang, E. *Scientific and Regulatory Considerations for Synthetic Peptides Referencing Peptide Drug Products of rDNA Origin*. Presentation at 4th USP Workshop on Synthetic Therapeutic Peptides: Regulations, Standards and Quality. Rockville, MD, Nov. 6, 2017.
79. Pang, E. *Resolving Peptide Drug Challenges Through Pre-ANDA Processes*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.
80. Patel, N. *Skin in the Game: Mechanistic Modeling of Dermal Drug Absorption*. Presentation at the Certara Blog: PBPK Modeling & Simulation. Mar. 2, 2018.
81. Peters, J. *Demonstrating Dermatological Bioequivalence Beyond the In Vivo Clinical Endpoint Bioequivalence Study*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access. White Oak, MD, Oct. 20, 2017.
82. Price, R. *Dissolution and Beyond: The Use of Advanced Structural Characterization Tool for Demonstrating Pharmaceutical Equivalence of Orally Inhaled Drug Products*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.
83. Singh, N., Kannan, R., and Przekwas, A. *A Multiscale Computational Framework for Inhalation Pharmacology and Drug Development*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.
84. Qin, B. *Considerations for Establishing Q1/Q2 Sameness of Complex Formulations*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.
85. Ramezanli, T. *Product Development Considerations for Transdermal/Topical Delivery Systems*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 13, 2018.
86. Raney, S. *The Journey from Developing the Research Studies to Drafting a New Regulatory Standard: A Case Study with Acyclovir Cream*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and

Improving Patient Access. White Oak, MD, Oct. 20, 2017.

87. Raney, S. *Strategies to Improve Patient Access to High Quality Topical Products*. Presentation at American Association of Pharmaceutical Scientists Annual Meeting Workshop: Dermatological Drug Products: Developmental & Regulatory Considerations. San Diego, CA, Nov. 12, 2017.
88. Raney, S. *FDA Regulatory Initiatives Related to Generic Dermatological and Transdermal Drug Products*. Presentation at 30th Anniversary Perspectives in Percutaneous Penetration Conference. LaGrande-Motte, France, Apr. 5, 2018.
89. Raney, S. *FDA Champions Research to Make Complex Generic Transdermal Products Available to Patients*. Presentation at DIA Webinar. Silver Spring, MD, Apr. 25, 2018.
90. Raney, S. *Questions About the Proposed Topical Classification System (TCS), and What to Do with It.* Presentation at Product Quality Research Institute (PQRI). Silver Spring, MD, June 19, 2018.
91. Raney, S. *Overview of Current Science Based Regulatory Standards*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 13, 2018.
92. Roberts, M. *Correlation of Physicochemical Characteristics and In Vitro Permeation Tests (IVPT) Results for Acyclovir and Metronidazole Topical Products*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access. White Oak, MD, Oct. 20, 2017.
93. Roberts, M. *Mathematical Modeling of Skin Absorption and Transport: Foundation Lecture*. Presentation at American Association of Pharmaceutical Scientists Annual Meeting Workshop: Dermatological Drug Products: Developmental & Regulatory Considerations. San Diego, CA, Nov. 12, 2017.
94. Roberts, M. S. *Topical Semisolid Drug Product Critical Quality Attributes (Q3 Characterization) with Relevance to Topical Bioequivalence*. Presentation at Fifteenth International Conference on Perspectives in Percutaneous Penetration. LaGrande Motte, France, Apr. 5, 2018.
95. Roberts, M. *Topical Products: When Does a Difference Matter?* Presentation at GDUFA Regulatory Science Public Workshop. White Oak, MD, May 24, 2018.
96. Rodriguez, J. *Development of Enhanced Analytical Tools for Evaluation of Complex Generic Products*. Presentation at IFPAC. Bethesda, MD, Feb. 14, 2018.
97. Rodriguez, J. *Enhanced Analytical Tools for Bioequivalence Evaluation of Nasal Spray Drug Products*. Presentation at DIA Combination Products. Silver Spring, MD, Oct. 9, 2018.
98. Sailor, M. *In Vitro and In Vivo Characterization of Ophthalmic Suspensions*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.
99. Sakagami, M. *Discriminative In Vitro Dissolution Testing for Orally Inhaled Drug Products*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.
100. Sasisekharan, R. *Comparative Characterization of Highly Heterogeneous Drugs*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex

Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.

101. Schmidt, S. Presentation at Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review. Oct.2, 2017.

102. Schmidt, S. A Model – and Systems-Based Approach to Efficacy and Safety Questions Related to Generic Substitution. Presentation at GDUFA Regulatory Science Public Work- shop. White Oak, MD, May 24, 2018.

103. Schroeter, J. *A CFD-PBPK Approach to Simulate Deposition, Absorption, and Bioavailability of Intranasal Corticosteroids*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.

104. Schwendeman, S. *Formulation Characterization of PLGA Microspheres*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.

105. Sharan, S. *Evaluation of Residual Levonorgestrel As Potential Bioequivalence Metric for A Long Acting Intrauterine System Using Quantitative Modeling and Simulation Approach*. Presentation at American Association of Pharmaceutical Scientists Webinar. Webinar, MD, Oct. 12, 2017.

106. Sharan, S. *Application of Modeling and Simulation in Establishing Appropriate Bioequivalence Limits for Complex Formulations*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.

107. Shur, J. *Advanced Characterization Approaches to Demonstrate Bioequivalence of Nasal Suspension Drug Products*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.

108. Simamora, P. *In Vitro Bioequivalence Data for a Topical Product: Chemistry Review Perspective*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access. White Oak, MD, Oct. 20, 2017.

109. Singh, N., Kannan, R., and Przekwas, A. *A Multiscale Computational Framework for Inhalation Pharmacology and Drug Development*. Presentation at Public Workshop: New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Product. Jan. 9, 2018.

110. Sinner, F. *In Vivo Dermal Open Flow Microperfusion: A Novel Approach to Evaluating Topical Bioavailability and Bioequivalence*. Presentation at Topical Dermatological Generic Drug Products: Over- coming Barriers to Development and Improving Patient Access. White Oak, MD, Oct. 20, 2017.

111. Sinner, F. *Clinical Pharmacokinetic Evaluation of Dermal Bioavailability and Bioequivalence*. Presentation at American Association of Pharmaceutical Scientists Annual Meeting Workshop: Dermatological Drug Products: Developmental & Regulatory Considerations. San Diego, CA, Nov. 12, 2017.

112. Stamatopoulos, K. *In Silico Tools to Simulate Regional Differences of the Human GI Tract*. Presentation at Ungap Meeting. Leuven, Belgium, Mar. 9, 2018.

113. Stern, S. *Nanomedicine Pharmacokinetics and Bioanalytical Methods to Measure Drug Release*. Presentation at 11th World Drug Delivery Summit. Baltimore, MD, Oct. 16, 2017.

114. Stinchcomb, A. *Characterizing In Vitro Bioavailability of Acyclovir and Metronidazole Topical Products, and In Vitro-In Vivo Correlation Results with Transdermal Systems*. Presentation at Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access. White Oak, MD, Oct. 20, 2017.

115. Sun, D. *In Vitro and In Vivo Abuse Deterrence Evaluation of Generic Opioid Products*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 13, 2018.

116. Tsakalozou, E. *Use of Modeling for Assessment of BE for Topical Products*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 13, 2018.

117. Verthelyi, D. *Scientific Considerations for the Assessment Immunogenicity Risk of Generic Synthetic Peptide Products*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.

118. Walenga, R. *Computational Fluid Dynamics (CFD) Modeling for Product Development of Generic OINDPs and for Supporting Novel BE Approaches*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 13, 2018.

119. Walenga, R. *Computational Fluid Dynamics Modeling for Product Development of Generic OINDPs and for Supporting Novel BE Approaches*. Presentation at Complex Generic Drug Product Development Workshop. Sept. 13, 2018.

120. Wang, Y. *Characterization of Complex Excipients and Formulations*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.

121. Wang, X. *Identification and Quantitation of Host Cell Protein Impurities in Peptide Therapeutics Using Liquid Chromatography-Mass Spectrometry*. Presentation at 4th USP Workshop on Synthetic Therapeutic Peptides: Regulations, Standards and Quality. Rockville, MD, Nov. 6, 2017.

122. Wang, Y. *Development of Generic Long Acting Injectables: Regulatory Challenges and Considerations*. Presentation at Controlled Release Society (CRS) Annual Meeting. New York, NY, July 22, 2018.

123. Wang, Y. *Considerations and Expectations for In Vitro Release Testing of Complex Formulations*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.

124. Witzmann, K. *Predictive Dissolution Methods From OINDPs*. Presentation at Public Workshop: New Insights From Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products. Jan. 9, 2018.

125. Witzmann, K. *Overcoming Barriers to Entry for Complex Generic Oral Inhalation Drug Products*. Presentation at DIA Webinar. Silver Spring, MD, Mar. 15, 2018.

126. Witzmann, K. *The Role of Comparative Analyses for Evaluation of Generic Drug-Device Combinations in an ANDA*. Presentation at RDD 2018. Tuscon, AZ, Apr. 26, 2018.

127. Witzmann, K. *Generic Drug Development for Respiratory Products, US Food and Drug Administration Update*. Presentation at ATS 2018. San Diego, CA, May 23, 2018.

128. Witzmann, K. *Overview of Regulatory and User-Interface Considerations, and the Role of Comparative Analyses, in Developing a Generic Drug-Device Combination Product in an ANDA*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.

129. Witzmann, K. *Generic Drug Development for Respiratory Products, US Food and Drug Administration Update*. Presentation at ATS 2018 Session L25. May 23, 2018.

130. Zhang, D. *Demonstrating Complex API Sameness*. Presentation at Public Workshop: Demonstrating Equivalence of Generic Complex Drug Substances and Formulations. White Oak, MD, Oct. 6, 2017.

131. Zhang, L. *Opening Remarks*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.

132. Zhang, L. *FDA Research Update on the FY18 Initiatives*. Presentation at Fy2018 Generic Drug Regulatory Science Initiatives Public Workshop. Silver Spring, MD, May 24, 2018.

133. Zhang, L. *Generic Drug Reflection Paper*. Presentation at IPRP Management Committee Meeting. Kobe, Japan, June 2, 2018.

134. Zhang, L. *Generic Drug Reflection Paper*. Presentation at ICH Management Committee Meeting. Kobe, Japan, June 4, 2018.

135. Zhang, L. *Generic Drug Reflection Paper*. Presentation at ICH Assembly. Kobe, China, June 6, 2018.

136. Zhang, L. *Pre-ANDA Program Overview*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.

137. Zhang, D. *Considerations in Demonstrating Complex API Sameness*. Presentation at Complex Generic Drug Product Development Workshop. Silver Spring, MD, Sept. 12, 2018.

138. Zhang, L. *Influx Intestinal Transporters: A Missing Piece in the Puzzle?* Presentation at ACCP Annual Meeting. Bethesda, MD, Sept. 22, 2018.

139. Zhao, L. *Leveraging Quantitative Methods and Modeling to Modernize*. Presentation at Leveraging Quantitative Methods and Modeling to Modernize Generic Drug Development and Review. White Oak, MD, Oct. 2, 2017.

140. Zhao, L. *Application of Quantitative Methods and Modeling to Generic Drug Development*. Presentation at International Symposium of Quantitative Pharmacology. Beijing, China, Dec. 1, 2017.

141. Zhao, L. *Session 4: Computational Models to Understand In Vivo Performance of OINDPs*. Presentation at OINDP Workshop. Silver Spring, MD, Jan. 9, 2018.

142. Zhao, L. *Big Data Application in Life Sciences*. Presentation at Chinese Biopharmaceutical Association. Rockville, MD, Feb. 3, 2018.

143. Zhao, L. *Application of Quantitative Methods and Modeling to Generic Drug Development*. Presentation at College of Pharmacy, Taipei Medical University. Taipei,

ROC, Apr. 20, 2018.

144. Zhao, L. *Pioneering Modeling Methodologies in Generic Drug Development*. Presentation at DIA Webinar. Silver Spring, MD, May 17, 2018.

145. Zhao, L. *Challenges and Opportunities in Data Access and Methodology Development for Post-Market Generic Drug Monitoring*. Presentation at Drug Information Association (DIA) Annual Meeting. Boston, MA, June 24, 2018.

146. Zhao, L. *Predicting Future Generic Drug Competition: Powering Strategic Planning Using Quantitative Methods and Modeling*. Presentation at Drug Information Association (DIA) Annual Meeting. Boston, MA, June 24, 2018.

147. Zhao, L. *A Model- & Systems-Based Approach to Assess & Ensure Generic Substitution*. Presentation at ACCP Annual Meeting. Bethesda, MD, Sept. 23, 2018.