FDA Office of Generic Drugs Office of Research & Standards (ORS)
Presentations by External Collaborators and ORS Staff in Fiscal Year 2013

1. Berg MJ. Lamotrigine, a narrow therapeutic index drug or not? American Academy of Neurology, San Diego, CA, March 16-23, 2013.
2. Brasseur JG, Wang Y. Hydrodynamic Enhancements of Dissolution from Drug Particles: In vivo vs In vitro, 66th Annual Meeting of the American Physical Society (APS) Division of Fluid Dynamics, Pittsburgh, PA, November 26, 2013.
3. Choi S. An Assessment of FDA's Dose-Scaling Approach to Evaluate Pharmacodynamic Equivalence, Respiratory Drug Delivery (remote), Berlin, Germany, May 15, 2013.
4. Elder EJ, et al. Identification of the most disparate generic lamotrigine tablets based on in vitro screening, 67th Annual Meeting of the American Epilepsy Society, Washington, DC, December 6-10, 2013.
5. Jiang W. Pharmaceutical Quality and Bioequivalence of Generic Mycophenolate Mofetil Tablets, American Transplant Congress, Seattle, WO, June 15, 2013.
6. Jiang X. Generic Drugs for Epilepsy Patients: Ensuring Therapeutic Equivalence, American Epilepsy Society's Annual Meeting, Washington, DC, December 15, 2013.
7. Lionberger R. Biopharmaceutics of Non-Orally Administrated Drugs, AAPS Webinar, San Antonio, TX, November 21, 2013.
8. Lionberger R. Challenges of Assessing Bioequivalence of Topical Pharmaceutical Products, "PQRI Workshop on the Evaluation of New and Generic Topical Drug Products - Current Challenges in Bioequivalence, Quality, and Novel Assessment Technologies, "Rockville, MD, March 15, 2013.
9. Lionberger R. Complex Generic Drugs, GPhA Fall Technical Meeting, Bethesda, MD, October 15, 2013.
10. Lionberger R. GDUFA Regulatory Science, GPhA/FDA CMC Workshop, Bethesda, MD, June 15, 2013.
11. Lionberger R. Innovative Approaches to Evaluation of Topical Product Bioequivalence, "PQRI Workshop on the Evaluation of New and Generic Topical Drug Products - Current Challenges in Bioequivalence, Quality, and Novel Assessment Technologies, Rockville, MD, March 15, 2013.
12. Lionberger R. New OGD Guidance: Bioequivalence Recommendations for Inhaled Products, AAPS Workshop on Inhaled Drug Products, Rockville, MD, September 09, 2013.
13. Lionberger R. Research initiatives in FDA's Office of Generic Drugs, M-CERSI Day, Baltimore, MD, September 15, 2013.
14. Polli JE, Ting TY, Jiang W. What a "drop-out" reveals about the nocebo effect in epilepsy patients, Abstracts of the Annual Meeting of the American Epilepsy Society, Washington, DC, December 5-9, 2013.
15. Saluja B. Overview of FDA research interests in dissolution of inhaled products, Joint Pharmaceutical Analysts Group (JPAG) Symposium, June 15, 2013.
16. Saluja B. Rationale behind the recent Draft Guidance on Fluticasone Propionate; Salmeterol Xinafoate., Drug Delivery to Lung Conference (remote), December 15, 2013.

17. Ting TY, Jiang W, Krumholz A, Polli JE. Feasibility of assessing antiepileptic drug bioequivalence in patients with epilepsy under clinical use conditions, Abstracts of the Annual Meeting of the American Epilepsy Society, Washington, DC, December 6-10, 2013.
18. Welty TE, et al. Comparison of bioavailability and dissolution data for generic lamotrigine tablets in the EQUIGEN trial, 67th Annual Meeting of the American Epilepsy Society, Washington, DC, December 6-10, 2013.
19. Zhang X. PBPK as a New Tool in Regulatory Reviews: Latest Absorption and Biopharmaceutics Applications, AAPS annual meeting, San Antonio, TX, November 15, 2013.
20. Zheng N, Jiang W, Lionberger R, Zhang X. Modeling and simulation of iron transport after single dose of iron colloid injection, American Association of Pharmaceutical Scientists Annual Meeting, San Antonio, TX, November, 2013.