Office of Generic Drugs  
Office of Research and Standards  
Division of Therapeutic Performance Presents:

New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products (OINDPs)

January 09, 2018  
FDA White Oak Campus,  
10903 New Hampshire Ave.  
Bldg. 31, Rm. 1503 Sections B & C  
Silver Spring, MD 20993

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<th>Time</th>
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| 8:30 am to 8:40 am | Opening Remarks  
Lei Zhang, PhD  
Deputy Director, Office of Research and Standards  
OGD/CDER/FDA |
| 8:40 am to 9:00 am | GDUFA Regulatory Science Initiatives for Generic OINDPs  
Renishkumar Delvadia, PhD  
Reviewer, Division of Therapeutic Performance  
ORS/OGD/CDER/FDA |
| 9:00 am to 9:05 am | Session Introduction  
Kimberly Witzmann, M.D. (Session Chair)  
Team Lead, Division of Therapeutic Performance  
ORS/OGD/CDER/FDA |
| 9:05 am to 9:30 am | Development of an Optimized Dissolution Test System for OINDPs  
Guenther Hochhaus, PhD  
Professor, College of Pharmacy,  
University of Florida, USA |
| 9:30 am to 9:55 am | Discriminative In Vitro Dissolution Testing for Orally Inhaled Drug Products: Transwell-based System  
Masahiro Sakagami, PhD  
Associate Professor, School of Pharmacy,  
Virginia Commonwealth University, USA |
| 9:55 am to 10:15 am | Break |
| 10:15 pm to 10:40 am | Dissolution and Beyond: The Use of Advanced Characterization Tools for Demonstrating Pharmaceutical Equivalence of Orally Inhaled Drug Products:  
Robert Price, PhD  
Professor, Dept. of Pharmacy and Pharmacology  
University of Bath, UK |
Panel Discussion: Role of Dissolution in Development and Bioequivalence Assessment of Orally Inhaled Drug Products
Paul Seo, PhD (DB/ONDOP/OPQ/CDER/FDA)
Dhaval Gaglani, PhD (DMRP/OLDP/OPQ/CDER/FDA)
Bing Li, PhD (DBI/OB/OGD/CDER/FDA)
Robert Lionberger, PhD (ORS/OGD/CDER/FDA)
Markham Luke, M.D., PhD (DTP/ORS/OGD/CDER/FDA)
Guenther Hochhaus, PhD (University of Florida)
Masahiro Sakagami, PhD (Virginia Commonwealth University)
Robert Price, PhD (University of Bath)

Lunch Break

Session 2: Novel Analytical Tools for Characterization of Nasal Suspensions

Session Introduction
Xiaohui Jiang, PhD (Session Chair)
Deputy Director, Division of Therapeutic Performance
ORS/OGD/CDER/FDA

Analytical Method Development for Ingredient-Specific Particle Sizing of Nasal Spray Suspensions
Changning Guo, PhD
Research Chemist, Division of Pharmaceutical Analysis
OTR/OPQ/CDER/FDA

Advanced Characterization Approaches to Demonstrate Bioequivalence of Nasal Suspension Drug Products
Jag Shur, PhD
Research Fellow, Dept. of Pharmacy and Pharmacology
University of Bath, UK

Questions from Participants

Session 3: Realistic Models for Prediction of Regional Drug Deposition from OINDPs

Session Introduction
Markham Luke, M.D., PhD (Session Chair)
Director, Division of Therapeutic Performance
ORS/OGD/CDER/FDA

Clinically Relevant In Vitro Testing of Oral Inhalation Products Using Realistic Mouth-Throat Models
Peter Byron, PhD
Professor Emeritus, School of Pharmacy
Virginia Commonwealth University, USA

Comparing Nasal Suspension Products Using Realistic In Vitro Test Methods
Michael Hindle, PhD
Professor, School of Pharmacy
Virginia Commonwealth University, USA
### Session 4: Computational Models to Understand In Vivo Performance of OINDPs

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| 2:45 pm to 2:50 pm | **Session Introduction**  
Liang Zhao, PhD (Session Chair)  
Director, Division of Quantitative Methods and Modeling  
ORS/OGD/CDER/FDA |
| 2:50 pm to 3:15 pm | **A CFD-PBPK Approach to Simulate Deposition, Absorption, and Bioavailability of Intranasal Corticosteroids**  
Jeffry Schroeter, PhD  
Senior Scientist, Health Effects and Risk Assessment Group  
Applied Research Associates, USA |
| 3:15 pm to 3:40 pm | **A Multiscale Computational Framework for Inhalation Pharmacology and Drug Development**  
Andrzej Przekwas, PhD  
Chief Technology Officer and Senior Vice President  
CFD Research Corporation, USA |

### Panel Discussion: Future Direction of Generic OINDP Regulatory Science Research

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| 3:40 pm to 4:20 pm | **Session Chair: Robert Lionberger, PhD** (ORS/OGD/CDER/FDA)  
Badrul Chowdhury, M.D., PhD (DPARP/ODEII/OND/CDER/FDA)  
Dale Conner, PharmD. (OB/OGD/CDER/FDA)  
Sau Lee, PhD (OTR/OPQ/CDER/FDA)  
Liang Zhao, PhD (DQMM/ORS/OGD/CDER/FDA)  
Sarah Yim, M.D. (DCR/OB/OGD/CDER/FDA)  
Kimberly Witzmann, M.D. (DTP/ORS/OGD/CDER/FDA)  
Changning Guo, PhD (OTR/OPQ/CDER/FDA)  
Jag Shur, PhD (University of Bath)  
Peter Byron, PhD (Virginia Commonwealth University)  
Andrzej Przekwas, PhD (CFD Research Corporation)  
Michael Hindle, PhD (Virginia Commonwealth University)  
Jeffry Schroeter, PhD (Applied Research Associates) |
| 4:20 pm to 4:30 pm | **Closing Remarks**  
Robert Lionberger, PhD  
Director, Office of Research and Standards  
OGD/CDER/FDA |
## FDA’s Offices/Divisions

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<th>Abbreviation</th>
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<td>DB</td>
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