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

Introduction

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

Session 1: Predictive Dissolution Methods for OINDPs

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

10:40 am to 11:20 am	***Panel Discussion: Role of Dissolution in Development and Bioequivalence Assessment of Orally Inhaled Drug Products*** Paul Seo, PhD (DB/ONDP/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)
11:20 am to 12:30 pm	***Lunch Break***

Session 2: Novel Analytical Tools for Characterization of Nasal Suspensions

12:30 pm to 12:35 pm	***Session Introduction*** Xiaohui Jiang, PhD (Session Chair) Deputy Director, Division of Therapeutic Performance ORS/OGD/CDER/FDA
12:35 pm to 1:00 pm	***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
1:00 pm to 1:25 pm	***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
1:25 pm to 1:30 pm	***Questions from Participants***

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

1:30 pm to 1:35 pm	***Session Introduction*** Markham Luke, M.D., PhD (Session Chair) Director, Division of Therapeutic Performance ORS/OGD/CDER/FDA
1:35 pm to 2:00 pm	***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
2:00 pm to 2:25 pm	***Comparing Nasal Suspension Products Using Realistic In Vitro Test Methods*** Michael Hindle, PhD Professor, School of Pharmacy Virginia Commonwealth University, USA

2:25 pm to 2:30 pm	***Questions from Participants***
2:30 pm to 2:45 pm	***Break***

Session 4: Computational Models to Understand In Vivo Performance of OINDPs

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

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

DB	Division of Biopharmaceutics
DBI	Division of Bioequivalence I
DCR	Division of Clinical Review
DMRP	Division of Modified Release Products
DPA	Division of Pharmaceutical Analysis
DPARP	Division of Pulmonary, Allergy, and Rheumatology Products
DQMM	Division of Quantitative Methods and Modeling
DTP	Division of Therapeutic Performance
OB	Office of Bioequivalence
ODEII	Office of Drug Evaluation II
OGD	Office of Generic Drugs
OLDP	Office of Lifecyle Drug Products
OND	Office of New Drugs
ONDP	Office of New Drug Products
OPQ	Office of Pharmaceutical Quality
ORS	Office of Research and Standards
OTR	Office of Testing and Research