FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pharmaceutical Science and Clinical Pharmacology Advisory Committee (PSCP) Meeting
Omni Shoreham Hotel, The Ballroom
2500 Calvert St., NW, Washington, District of Columbia
March 15, 2017

DRAFT AGENDA

The use of model-informed drug development (MIDD) for new and generic drugs has significantly increased over the past several years. The committee will discuss strategies, approaches, and challenges in MIDD with specific focus on two areas. During the morning session, the committee will discuss approaches and evidentiary information needed for applying physiologically-based pharmacokinetic modeling and simulation throughout a drug's lifecycle. During the afternoon session, the committee will discuss mechanistic model-informed safety evaluation with a focus on drug potential for causing arrhythmias. The Comprehensive in Vitro Proarrhythmia Assay will be discussed as an examplar.

7:30 a.m.	Call to Order and Introduction of Committee	**Scott Waldman, MD, PhD** Chairperson, PSCP
7:35 a.m.	Conflict of Interest Statement	**Jennifer Shepherd, RPh** Designated Federal Officer, PSCP
7:45 a.m.	Model-Informed Drug Development (MIDD): Opportunities and Challenges	**Issam Zineh, PharmD, MPH** Director, Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS), CDER, FDA
Session I:	**ROLE FOR PHYSIOLOGICALLY-BASED PHARMACOKINETIC (PBPK) MODELING AND SIMULATION IN DRUG DEVELOPMENT AND REGULATION**	
8:00 a.m.	**FDA PRESENTATIONS**	
	Towards Consistent Regulatory Assessment of Physiologically-based Pharmacokinetic (PBPK) Modeling to Support Dosing Recommendations	**Ping Zhao, PhD** PBPK Lead, Division of Pharmacometrics OCP, OTS, CDER, FDA
8:20 a.m.	Absorption PBPK Modeling and Applications to Support Formulation and Generic Drug Development	**Liang Zhao, PhD** Division Director, Division of Quantitative Methods & Modeling Office of Research and Standards Office of Generic Drugs (OGD), CDER, FDA
8:40 a.m.	**GUEST SPEAKER PRESENTATIONS**	
	PBPK Submissions and Review Experience in European Medicines Agency (EMA) and EMA Draft PBPK Guideline	**Anna Nordmark, PhD** Pharmacokinetic Assessor Medical Products Agency, Sweden Member of the Modelling and Simulation Working Group, European Medicines Agency (EMA) Rapporteur of the EMA PBPK Guideline

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DRAFT AGENDA (CONT.)

GUEST SPEAKER PRESENTATIONS (CONT.)

9:00 a.m.	Experience, Opportunity, and Challenges in Submitting PBPK Analyses to Regulators, and Comments to EMA and FDA Draft PBPK Guidance Documents	**Neil Parrott, PhD** Distinguished Scientist Roche Pharma Research and Early Development Roche Innovation Center Basel, Switzerland Leader, The Innovation & Quality (IQ) Consortium Working Group on PBPK Guidances
9:20 a.m.	Clarifying Questions	
9:35 a.m.	**BREAK**	
9:45 a.m.	Open Public Hearing Session I	
10:15 a.m.	Questions to the Committee/Committee Discussion I	
11:15 a.m.	**LUNCH BREAK**	

Session II: MECHANISTIC MODEL-INFORMED SAFETY EVALUATION: COMPREHENSIVE IN VITRO PROARRHYTHMIA ASSAY (CIPA) AS AN EXAMPLE

12:05 p.m.	Call to Order and Introduction of Committee	**Scott Waldman, MD, PhD** Chairperson, PSCP
	Conflict of Interest Statement	**Jennifer Shepherd, RPh** Designated Federal Officer, PSCP
12:10 p.m.	**FDA PRESENTATION**	
	Overview of the ICH E14 Guideline and its Implementation within FDA	**Christine Garnett, PharmD** Clinical Analyst and QT Lead Division of Cardiovascular and Renal Products Office of Drug Evaluation I, Office of New Drugs, CDER, FDA
12:30 p.m.	**GUEST SPEAKER PRESENTATIONS**	
	The Need for and Overview of the Proposed Comprehensive In Vitro Proarrhythmia Assay	**Gary Gintant, PhD** Senior Research Fellow Department of Integrative Pharmacology Abbvie

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DRAFT AGENDA (CONT.)

GUEST SPEAKER PRESENTATIONS (CONT.)

12:50 p.m.	Background and Rationale for Mechanistic Cardiac Electrophysiology Models	**Gary Mirams, PhD** Sir Henry Dale Fellow Centre for Mathematical Medicine and Biology University of Nottingham, United Kingdom
1:05 p.m.	**FDA PRESENTATIONS**	
	CiPA In Silico Modeling Development Strategy and Results	**Zhihua Li, PhD** Staff Fellow Division of Applied Regulatory Science OCP, OTS, CDER, FDA
1:20 p.m.	Phase 1 Electrocardiogram (ECG) Analysis under CiPA, Integration of All CiPA Components, and Potential Implementation Strategy	**David Strauss, MD, PhD** Division Director Division of Applied Regulatory Science OCP, OTS, CDER, FDA
1:40 p.m.	Clarifying Questions	
1:55 p.m.	**BREAK**	
2:05 p.m.	Open Public Hearing Session II	
2:35 p.m.	Questions to the Committee/Committee Discussion II	
3:35 p.m.	**CONCLUDING REMARKS**	**Kathleen Uhl, MD** Director OGD, CDER, FDA
3:45 p.m.	**ADJOURNMENT**	