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

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP) Meeting
Bethesda North Marriott Hotel and Conference Center
White Oak Room, 5701 Marinelli Road, Bethesda, Maryland
September 25, 2013

AGENDA

The committee will discuss optimal strategies for the evaluation, interpretation, and communication of drug-drug interaction (DDI) information. FDA will seek input on: (1) best practices in DDI communication through prescription drug product labels (i.e., "package inserts"), namely: a) appropriate format for presentation (e.g. tables, graphs, text) of DDI information; b) level of detail of DDI study results; and c) appropriate wording for clinical recommendations based on empirical data vs. anticipated interactions; (2) appropriate criteria for determining whether or not to describe DDI information derived from the literature in product labels; and (3) how package insert information on DDIs is used by various end-users (e.g., prescribers, dispensers, DDI database curators) in decision making and/or communication.

8:00 a.m.	Call to Order and Introduction of Committee	**Jeffrey Barrett, PhD, FCP** Acting Chairperson, ACPS-CP
8:05 a.m.	Conflict of Interest Statement	**Yvette Waples, PharmD** Designated Federal Officer, ACPS-CP
8:15 a.m.	Introduction and Background	**Issam Zineh, PharmD, MPH** Director, Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS), CDER, FDA
8:25 a.m.	**GUEST SPEAKER PRESENTATION**	
	Drug Labels and Interactions on the Front Lines	**David Juurlink, MD, PhD** Associate Professor Department of Medicine, University of Toronto Attending Physician, Division of General Internal Medicine Sunnybrook Health Sciences Centre Scientist, Institute for Clinical Evaluative Sciences Toronto, Ontario
8:55 a.m.	**FDA PRESENTATIONS**	
	Communicating Drug Interaction Information: Drug Labeling	**Kellie Schoolar Reynolds, PharmD** Deputy Director, Division of Clinical Pharmacology IV OCP, OTS, CDER, FDA
9:30 a.m.	Inclusion of Literature-Based Drug Interaction Information into FDA Drug Labeling	**Lei Zhang, PhD** Special Assistant to the Office Director OCP, OTS, CDER, FDA
9:50 a.m.	Clarifying Questions	
10:05 a.m.	**BREAK**	

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AGENDA (cont.)

10:20 a.m.	**SPEAKER PRESENTATION**	
	Update- Health IT Initiative on Drug Interactions	**Tricia Wilkins, PharmD, PhD** Project Officer, Beacon Community Program Office of the National Coordinator for Health IT (ONC) Washington, District of Columbia
10:30 a.m.	**GUEST SPEAKER PRESENTATIONS**	
	Best Practices in DDI - Related Content and Management	**David W. Bates, MD, MSc** Medical Director of Clinical and Quality Analysis, Partners Healthcare Chief Quality Officer, and Chief, Division of General Medicine Brigham and Women's Hospital Boston, Massachusetts
11:00 a.m.	Strategies for Improving Drug Interaction Alerts for Clinical Decision Support (CDS)	**Karl Matuszewski, PharmD, MS** Vice President, Clinical Editorial First Databank, Inc. (FDB) South San Francisco, California
11:30 a.m.	Clarifying Questions	
11:45 a.m.	**LUNCH**	
12:45 p.m.	Open Public Hearing Session	
1:45 p.m.	**BREAK**	
2:00 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	