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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
May 25, 2016

AGENDA

The committee will discuss the safety and efficacy of new drug applications (NDAs) 208673 for insulin glargine and lixisenatide injection, a fixed ratio drug product consisting of insulin and a GLP-1 receptor agonist, and 208471 for lixisenatide injection, a GLP-1 receptor agonist, submitted by Sanofi Aventis c/o Sanofi U.S. Services Inc., proposed for the treatment of adults with type 2 diabetes mellitus.

8:00 a.m.	Call to Order and Introduction of Committee	**Robert Smith, MD** Chairperson, EMDAC
8:05 a.m.	Conflict of Interest Statement	**LaToya Bonner, PharmD** Designated Federal Officer, EMDAC
8:10 a.m.	FDA Introductory Remarks	**Jean-Marc Guettier, MDCM** Director Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**APPLICANT PRESENTATIONS**	**Sanofi Aventis, Inc.**
	Introduction	**Paul Chew, MD** Senior VP Research and Development Sanofi
	Need for Treatment Options	**Neil Skolnik, MD** Temple University School of Medicine
	MoA Lixisenatide and iGlarLixi	**John Newton, PhD** VP Pharmacokinetics, Dynamics Sanofi
	Efficacy of Lixisenatide and iGlarLixi	**Rachele Berria, MD, PhD** VP Head Diabetes Medical Unit Sanofi
	Safety of Lixisenatide and iGlarLixi	**Kristen Sharma, MD** VP Global Diabetes and CV Pharmacovigilance Unit Sanofi

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Contribution and Component Titration and Dose Capping	**Rene Belder, MD** Global Project Head Sanofi
	Benefit Risk	**Luigi Meneghini, MD** University of Texas Southwestern Medical Center
9:50 a.m.	Clarifying Questions to Applicant	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	LIXISENATIDE	
	Introduction and Regulatory History Summary of Efficacy and Safety	**Suchitra Balakrishnan, MD, PhD** Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA
	Cardiovascular Outcome Trial (ELIXA) Results	**Yueqin Zhao, PhD** Mathematical Statistician Division of Biometrics VII (DB-VII) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER FDA
	LIXISENATIDE/INSULIN GLARGINE FIXED RATIO COMBINATION (IGLARLIXI)	
	Introduction to the Combination Product	**Suchitra Balakrishnan, MD, PhD**
	Efficacy of the Combination Product	**Jiwei He, PhD** Mathematical Statistician Division of Biometrics II (DB-II) OB, OTS, CDER, FDA
	Secondary Endpoints Safety Generalizability and Clinical Considerations	**Suchitra Balakrishnan, MD, PhD**

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FDA PRESENTATIONS (CONT.)

	Human Factors Evaluation	**Ariane Conrad, PharmD, BCACP, CDE, FASCP** Safety Evaluator Division of Medication Error Prevention and Analysis Office of Medication Error Prevention and Risk Management (OMEPRM) Office of Surveillance and Epidemiology (OSE) CDER FDA
	Summary	**Suchitra Balakrishnan, MD, PhD**
11:50 a.m.	Clarifying Questions to FDA	
12:05 p.m.	**LUNCH**	
1:05 p.m.	**OPEN PUBLIC HEARING**	
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	