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 24, 2016

DRAFT AGENDA

The committee will discuss the safety and efficacy of new drug application (NDA) 208583 for insulin degludec and liraglutide injection, submitted by Novo Nordisk Inc., for the proposed indication: adjunct to diet and exercise to improve glycemic control in 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**	**Novo Nordisk, Inc.**
	Introduction	**Robert Clark** Vice President, Regulatory Affairs Novo Nordisk
	Rationale for the New Treatment Strategy	**Christopher Sorli, MD** Department Chair of Diabetes, Endocrinology and Metabolism Billings Clinic
	Efficacy	**Stephen Gough, MD** Senior Principal Clinical Scientist Novo Nordisk
	Safety	**Todd Hobbs, MD** Chief Medical Officer Novo Nordisk
	Benefit-Risk Summary	**Stephen Gough, MD**
9:50 a.m.	Clarifying Questions to Applicant	
10:05 a.m.	**BREAK**	

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DRAFT AGENDA (cont.)

10:20 a.m.	**FDA PRESENTATIONS**	
	Clinical and Statistical Overview	**Tania Condarco, MD** Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA
		Anna Kettermann, Dipl. Math, MA Mathematical Statistician Division of Biometrics II (DB-II) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	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
11:50 p.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**	