

**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

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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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

Biostatistician

Division of Biostatistics II (DB-II)

Office of Biostatistics (OB)

Office of Translational Sciences (OTS), CDER, FDA

Human Factors Evaluation

Ariane O. Conrad, PharmD, BCACP, CDE

Safety Evaluator

Division of Medication Error Prevention and Analysis
(DMEPA)

Office of Medication Error Prevention and Risk
Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

CDER, FDA

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**