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
June 20, 2017

DRAFT AGENDA

The committee will discuss a supplemental new drug application for VICTOZA (liraglutide) injection (NDA 022341), sponsored by Novo Nordisk, for the proposed additional indication of: as an adjunct to standard treatment of cardiovascular risk factors to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and high cardiovascular risk.

8:00 a.m.	Call to Order and Introduction of Committee	**Peter Wilson, 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, MD** 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
	LEADER Clinical Design	**Steve Marso, MD** Medical Director, Cardiovascular Services HCA Midwest Health Heart and Vascular Institute
	CVOT Results	**Alan Moses, MD** Global Chief Medical Officer Novo Nordisk
	Safety	**Todd Hobbs, MD** US Chief Medical Officer Novo Nordisk
	Clinical Implications	**John Buse, MD, PhD** Verne S. Caviness Distinguished Professor Chief, Division of Endocrinology University of North Carolina School of Medicine

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DRAFT AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Benefit-Risk	**Alan Moses, MD**
9:50 a.m.	Clarifying Questions to Applicant	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	Clinical and Statistical Overview	**Tania Condarco, MD** Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA **Kiya Hamilton, PhD** Mathematical Statistician Division of Biostatistics II (DB-II) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Safety Overview	**Julie Golden, MD** Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA **Shannon Sullivan, MD, PhD** Clinical Reviewer DMEP, ODE-II, OND, 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	
3:45 p.m.	**BREAK**	
4:00 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	