

**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

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

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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
June 20, 2017

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 Efficacy Overview | Tania Andrea Condarco, MD
Clinical Reviewer
DMEP, ODE-II, OND, CDER, FDA |
| | Statistical Efficacy Summary | Kiya Hamilton, PhD
Mathematical Statistician
Division of Biostatistics II (DB-II)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA |
| | Clinical Safety Summary | Julie K. Golden, MD
Clinical Reviewer
DMEP, ODE-II, OND, CDER, FDA |
| | Clinical Safety Summary: Medullary
Thyroid Cancer | 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 | |