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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
Tommy Douglas Conference Center
10000 New Hampshire Avenue, Silver Spring, Maryland
October 18, 2017

AGENDA

The committee will discuss the safety and efficacy of new drug application (NDA) 209637 for semaglutide injection, submitted by Novo Nordisk, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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, NCPS** Designated Federal Officer, EMDAC
8:10 a.m.	FDA Introductory Remarks	**William Chong, MD** Clinical Team Lead 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.	**NIH PRESENTATION**	
	Review of Medical Risk Factors Associated with Diabetic Retinopathy	**Emily Y. Chew, MD** Deputy Director Division of Epidemiology and Clinical Applications National Eye Institute, National Institutes of Health
8:35 a.m.	Clarifying Questions to Guest Speaker	
8:40 a.m.	**APPLICANT PRESENTATIONS**	**Novo Nordisk Inc.**
	Introduction	**Stephanie DeChiaro** Director, Regulatory Affairs Novo Nordisk
	Design, Efficacy and Primary Outcomes	**Anders Hvelplund, MD, PhD** Senior Director, Medical and Science Novo Nordisk
	Safety	**Stephen Gough, MD, FRCP (UK)** Senior Principal Clinical Scientist Novo Nordisk

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Diabetic Retinopathy	**Lloyd Paul Aiello, MD, PhD** Professor and Vice Chair Department of Ophthalmology Harvard Medical School Director, Beetham Eye Institute and Vice President Joslin Diabetes Center
	Retinal Safety	**Stephen Gough, MD, FRCP (UK)**
	Clinical Perspective	**Richard Pratley, MD** Samuel E. Crockett, MD Chair in Diabetes Research Director, Florida Hospital Diabetes Institute Senior Scientist, Translational Research Institute for Metabolism and Diabetes
	Benefit:Risk	**Stephen Gough, MD, FRCP (UK)**
10:10 a.m.	Clarifying Questions to Applicant	
10:25 a.m.	**BREAK**	
10:40 a.m.	**FDA PRESENTATIONS**	
	FDA Overview of Efficacy and Safety of Semaglutide	**Andreea Lungu, MD** Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA
	Statistical Assessment of Cardiovascular Safety and Retinopathy Safety of Semaglutide in the SUSTAIN 6 Trial	**Ya-Hui Hsueh, PhD** Mathematical Statistician Division of Biometrics VII Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Further Discussion of Findings for Diabetic Retinopathy	**Andreea Lungu, MD**
	Summary of FDA Findings for Semaglutide	**Andreea Lungu, MD**
11:45 a.m.	Clarifying Questions to FDA	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	

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AGENDA (cont.)

2:00 p.m. Questions to the Committee/Committee Discussion

3:45 p.m. **BREAK**

4:00 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**