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
October 24-25, 2018

AGENDA

On both days, the committee will discuss the "Guidance for Industry: Diabetes Mellitus – Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes" (https://www.fda.gov/downloads/Drugs/Guidances/ucm071627.pdf), and the cardiovascular risk assessment of drugs and biologics for the treatment of type 2 diabetes mellitus.

Day 1: Wednesday, October 24, 2018

8:30 a.m.	Call to Order and Introduction of Committee	**Peter Wilson, MD** Chairperson, EMDAC
8:35 a.m.	Conflict of Interest Statement	**LaToya Bonner, PharmD** Designated Federal Officer, EMDAC
8:40 a.m.	FDA Introductory Remarks	**William Chong, MD** Director (Acting) Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:50 a.m.	**FDA PRESENTATIONS**	
	History of the 2008 Cardiovascular Guidance and Overview of the Guidance Recommendations	**Lisa Yanoff, MD** Deputy Director (Acting) DMEP, ODE-II, OND, CDER, FDA
	Review of Cardiovascular Assessments Prior to the 2008 Guidance	**Patrick Archdeacon, MD** Clinical Team Lead (Acting) DMEP, ODE-II, OND, CDER, FDA
	Review of Design and Results of Cardiovascular Outcome Trials	**Tania Condarco, MD** Clinical Team Lead (Acting) **Mahtab Niyyati, MD** Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA
10:15 a.m.	Clarifying Questions to FDA	
10:30 a.m.	**BREAK**	

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AGENDA (cont.)

10:45 a.m.	**GUEST SPEAKER PRESENTATION**	
	After 10 Years and 26 CVOTs, Where Do We Stand on CV Safety in Diabetes	**Robert E. Ratner, MD** Professor of Medicine Division of Endocrinology Georgetown University School of Medicine
11:15 a.m.	Clarifying Questions for Dr. Ratner	
11:45 a.m.	Additional Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**TIMI STUDY GROUP PRESENTATION**	
	Cardiovascular Outcome Trials in Patients with Diabetes: Issues and Opportunities	**Marc S. Sabatine, MD, MPH** Chairman, TIMI Study Group Lewis Dexter, MD Distinguished Chair in Cardiovascular Medicine Brigham and Women's Hospital Professor of Medicine, Harvard Medical School
1:30 p.m.	Clarifying Questions for Dr. Sabatine	
2:00 p.m.	**SPEAKER PRESENTATION**	
	Impact and Importance of the 2008 Guidance in Diabetes Care	**Jennifer B. Green, MD** Associate Professor of Medicine Division of Endocrinology, Metabolism and Nutrition Duke University Medical Center Duke Clinical Research Institute Durham VA Medical Center
2:30 p.m.	Clarifying Questions for Dr. Green	
3:00 p.m.	Additional Clarifying Questions	
3:30 p.m.	**ADJOURNMENT**	

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AGENDA (cont.)

Day 2: Thursday, October 25, 2018

8:30 a.m.	Call to Order and Introduction of Committee	**Peter Wilson, MD** Chairperson, EMDAC
8:35 a.m.	Conflict of Interest Statement	**LaToya Bonner, PharmD** Designated Federal Officer, EMDAC
8:40 a.m.	FDA Introductory Remarks	**William Chong, MD** Director (Acting) Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:50 a.m.	**OPEN PUBLIC HEARING**	
10:50 a.m.	**BREAK**	
11:05 a.m.	Questions to the Committee/Committee Discussion	
1:00 p.m.	**ADJOURNMENT**	