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 Niyayati, MD  Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA

10:15 a.m.  Clarifying Questions to FDA

10:30 a.m.  BREAK
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
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