FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Endocrinologic and Metabolic Drugs Advisory Committee Meeting
Hilton Hotel, Silver Spring, Maryland
July 1 & 2, 2008

AGENDA

The committee will discuss the role of cardiovascular assessment in the pre-approval and post-approval settings for drugs and biologics developed for the treatment of type 2 diabetes mellitus.

8:00 – 8:05 a.m.	Call to Order and Introductions	**Kenneth Burman, MD** (Acting) Committee Chair Endocrinologic and Metabolic Drugs Advisory Committee
8:05 – 8:10 a.m.	Conflict of Interest Statement	**Paul Tran, RPh** Designated Federal Official Endocrinologic and Metabolic Drugs Advisory Committee
8:10 – 8:30 a.m.	Introduction/Background Overview of Day 1 Agenda	**Hylton Joffe, MD** FDA/CDER Division of Metabolism and Endocrinology Products
PRESENTATIONS:	**Guest Speaker Presentations**	
8:30 – 9:00 a.m.	Natural History of Type 2 Diabetes and Diabetes-Related Macrovascular Complications	**David Nathan, MD** Director of General Clinical Research Center and of Diabetes Center, Massachusetts General Hospital Professor of Medicine Harvard Medical School
9:00 – 9:10 a.m.	Panel questions to Dr. Nathan	
9:10 – 9:40 a.m.	Hemoglobin A1c as a Surrogate For Glycemic Control and Diabetes-Related Complications	**Robert Ratner, MD** Vice-President of Scientific Affairs MedStar Research Institute
9:40 – 9:50 a.m.	Panel questions to Dr. Ratner	
9:50 – 10:30 a.m.	Cardiovascular Outcome Trials: Statistical Considerations	**Thomas Fleming, PhD** Professor of Biostatistics University of Washington
10:30 – 10:45 a.m.	Panel questions to Dr. Fleming	
10:45 – 11:00 a.m.	**BREAK**	
11:00 – 11:30 a.m.	Clinical Macrovascular Outcomes with Anti-Diabetic Drugs: What we already Know	**Professor Rury Holman** Professor of Diabetic Medicine Diabetes Trials Unit Director OCDEM, University of Oxford
11:30 – 11:45 a.m.	Panel questions to Dr. Holman	
11:45 – 12:15 p.m.	Clinical Macrovascular Outcomes with Anti-diabetic drugs: Ongoing studies	**Hertzel Gerstein, MD** McMaster University Department of Medicine Hamilton, Ontario, Canada
12:15 – 12:30 p.m.	Panel questions to Dr. Gerstein	

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Endocrinologic and Metabolic Drugs Advisory Committee Meeting
Hilton Hotel, Silver Spring, Maryland
July 1 & 2, 2008

AGENDA

The committee will discuss the role of cardiovascular assessment in the pre-approval and post-approval settings for drugs and biologics developed for the treatment of type 2 diabetes mellitus.

Day 1 - July 1st

12:30 – 1:30 p.m.	**LUNCH BREAK**	
1:30 – 2:00 p.m.	Need for Cardiovascular Assessment During the Approval Process for Anti-Diabetic Drugs	**Steve Nissen, MD** Medical Director, Cleveland Clinic Cardiovascular Coordinating Center Department of Cardiovascular Medicine
2:00 – 2:15 p.m.	Panel questions to Dr. Nissen	
2:15 – 3:00 p.m.	Challenges in Designing a Cardiovascular Outcomes Trial in Patients with Type 2 diabetes	**Robert Califf, MD** Vice Chancellor for Clinical Research Duke University
3:00 – 3:15 p.m.	Panel questions to Dr. Califf	
3:15 – 3:30 p.m.	**BREAK**	
3:30 – 6:00 p.m.	Clarifications/questions from the Panel to The Speakers/Discussion	
6:00 p.m.	**ADJOURN**	

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Endocrinologic and Metabolic Drugs Advisory Committee Meeting
Hilton Hotel, Silver Spring, Maryland
July 1 & 2, 2008

AGENDA

The committee will discuss the role of cardiovascular assessment in the pre-approval and post-approval settings for drugs and biologics developed for the treatment of type 2 diabetes mellitus.

Day 2 – July 2nd

8:00 – 8:05 a.m.	Call to Order and Introductions	**Kenneth Burman, MD** (Acting) Committee Chair, Endocrinologic and Metabolic Drugs Advisory Committee
8:05 – 8:15 a.m.	Conflict of Interest Statement	**Paul Tran, RPh** Designated Federal Official Endocrinologic and Metabolic Drugs Advisory Committee
8:15 – 9:45 a.m.	Open Public Hearing	**TBD**
9:45 – 10:00 a.m.	FDA Remarks/Introductions to Day 2 Session	**Mary H. Parks, MD** Director, FDA/CDER Division of Metabolism and Endocrinology Products
10:00 – 10:15 a.m.	**BREAK**	
10:15 – 12:00 p.m.	Discussion/questions to the Committee	
12:00 – 1:00 p.m.	**LUNCH**	
1:00 – 2:45 p.m.	Continued discussion/questions to the Committee	
2:45 – 3:00 p.m.	**BREAK**	
3:00 – 4:30 p.m.	Continued discussion/questions to the Committee	
4:30 p.m.	**ADJOURN**	