

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

***Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) and the Drug Safety and Risk Management (DSaRM) Advisory Committee***  
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)  
White Oak Conference Center, Silver Spring, Maryland

June 5-6, 2013

**AGENDA**

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*On both days, the committees will discuss the results of an independent readjudication of the Rosiglitazone Evaluated for Cardiovascular Outcomes and Regulation of Glycemia in Diabetes (RECORD) trial, for new drug application (NDA) 21071, AVANDIA (rosiglitazone maleate) tablets. Rosiglitazone is a thiazolidinedione, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. AVANDIA is manufactured by GlaxoSmithKline.*

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**Day 1: June 5, 2013**

8:00 a.m.	<b>CALL TO ORDER AND INTRODUCTION OF COMMITTEE</b>	<b>Kenneth Burman, MD</b> Acting Chairperson
8:10 a.m.	<b>CONFLICT OF INTEREST STATEMENT</b>	<b>LCDR Minh Doan, PharmD</b> Acting Designated Federal Officer
8:15 a.m.	<b>FDA INTRODUCTORY REMARKS</b>	<b>Mary H. Parks, MD</b> Division Director Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	A Critical Review of the RECORD Re-adjudication	<b>Thomas A. Marciniak, MD</b> Medical Team Leader Division of Cardiovascular and Renal Products (DCRP), Office of Drug Evaluation I (ODE-I) OND, CDER, FDA
9:15 a.m.	Clarifying Questions	
9:25 a.m.	<b>SPONSOR PRESENTATIONS</b>  GlaxoSmithKline Presentation	<b>GlaxoSmithKline</b>  <b>Murray Stewart, DM, FRCP</b> GlaxoSmithKline
9:55 a.m.	Clarifying Questions	
10:05 a.m.	<b>BREAK</b>	

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10:20 a.m. **SPONSOR PRESENTATIONS (CONT.)**

Re-evaluation of RECORD Endpoints

**Kenneth Mahaffey, MD**

Associate Director of Duke Clinical Research  
Institute (DCRI)  
RECORD re-evaluation Principal Investigator

**Robert Bigelow, PhD**

DCRI Senior Statistician  
RECORD re-evaluation Senior Statistician

11:50 a.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. **FDA PRESENTATIONS**

Systematic Review of Epidemiologic Studies of  
Cardiovascular Risk in Patients Treated with  
Rosiglitazone or Pioglitazone – Update Since  
2010

**Kate Gelperin, MD, MPH**

Medical Reviewer  
Division of Epidemiology I  
Office of Pharmacovigilance and Epidemiology  
(OPE)  
Office of Surveillance and Epidemiology (OSE)  
CDER, FDA

1:30 p.m. Clarifying Questions

1:40 p.m. The Readjudication of Mortality and MACE  
From the RECORD Trial

**Preston M. Dunnmon, MD, FACP, FACC**

Medical Reviewer  
DCRP, ODE-I, OND, CDER, FDA

2:10 p.m. Clarifying Questions

2:20 p.m. The FDA Review of Cardiovascular  
Outcomes- An Overview

**Ellis F. Unger, MD**

Director  
ODE- I, OND, CDER, FDA

2:35 p.m. Clarifying Questions

2:45 p.m. **BREAK**

3:00 p.m. **FDA PRESENTATIONS (CONT.)**

FDA Statistical Analyses of RECORD  
Based on Re-adjudicated Outcomes

**Eugenio Andraca-Carrera, PhD**

Mathematical Statistician  
Division of Biometrics VII  
Office of Biostatistics  
Office of Translational Sciences, CDER, FDA

3:25 p.m. Clarifying Questions

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- 3:35 p.m.      How the Readjudication of RECORD      **Karen M. Mahoney, MD, FACE**  
Addressed Some of the Concerns From the      Diabetes Team Leader  
Original RECORD Reviews      DMEP, ODE-II, OND, CDER, FDA
- 4:05 p.m.      Clarifying Questions
- 4:15 p.m.      FDA Inspection of the      **Ann Meeker-O'Connell**  
Duke Clinical Research Institute (DCRI)      Acting Division Director  
Re-adjudication of the RECORD Trial      Division of Good Clinical Practice Compliance  
Office of Scientific Investigations  
Office of Compliance, CDER, FDA
- 4:40 p.m.      Clarifying Questions
- 5:00 p.m.      **ADJOURNMENT**

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**Day 2: June 6, 2013**

8:00 a.m.	<b>CALL TO ORDER AND INTRODUCTION OF COMMITTEE</b>	<b>Kenneth Burman, MD</b>
8:10 a.m.	<b>CONFLICT OF INTEREST STATEMENT</b>	<b>LCDR Minh Doan, PharmD</b>
8:15 a.m.	<b>FDA INTRODUCTORY REMARKS</b>	<b>Mary H. Parks, MD</b>
8:25 a.m.	<b>GUEST SPEAKER PRESENTATION</b>	
	Feasibility of a Clinical Outcomes Trial with Rosiglitazone Today	<b>Hertzel C. Gerstein, MD, MSc, FRCPC</b> Professor and Director Division of Endocrinology and Metabolism Population Health Research Institute at McMaster University and Hamilton Health Sciences Hamilton, Ontario, CANADA
8:55 a.m.	Clarifying Questions	
9:05 a.m.	<b>FDA PRESENTATIONS</b>	
	Rosiglitazone Risk Evaluation and Mitigation Strategy (REMS)	<b>Joyce Weaver, PharmD</b> Senior Drug Risk Management Analyst Division of Risk Management Office of Medication Error Prevention and Risk Management OSE, CDER, FDA
	Drug Utilization Patterns for Rosiglitazone- and Pioglitazone-Containing Products, July 2007-December 2012	<b>LT Justin A. Mathew, PharmD</b> Drug Utilization Data Analyst Division of Epidemiology II OPE, OSE, CDER, FDA
9:45 a.m.	Clarifying Questions	
10:00 a.m.	<b>BREAK</b>	
10:15 a.m.	<b>OPEN PUBLIC HEARING</b>	
11:15 a.m.	<b>COMMITTEE DISCUSSION</b>	
12:00 p.m.	<b>LUNCH</b>	
1:00 p.m.	<b>COMMITTEE DISCUSSION (CONT.)</b>	
2:00 p.m.	<b>CHARGE TO THE COMMITTEE</b>	<b>Mary H. Parks, MD</b>
2:10 p.m.	<b>COMMITTEE DISCUSSION/VOTE</b>	
5:00 p.m.	<b>ADJOURNMENT</b>	