

**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

**DRAFT 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 Readjudication (A Personal Perspective)	<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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**DRAFT AGENDA (cont.)**

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**

Update on New Epidemiologic Data Since the 2010 Advisory Committee

**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. Cardiology Review of Readjudication of Mortality and MACE From RECORD: Special Interest Topics for FDA

**Preston Dunmon, MD**

Medical Reviewer

DCRP, ODE-I, OND, CDER, FDA

2:10 p.m. Clarifying Questions

2:20 p.m. The FDA and 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**

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**DRAFT AGENDA (cont.)**

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

FDA Statistical Analyses of RECORD  
Based on Readjudicated 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

3:35 p.m. How the RECORD Readjudication  
Addressed Some of the Concerns From the  
Original RECORD Reviews

**Karen M. Mahoney, MD, FACE**  
Diabetes Team Leader  
DMEP, ODE-II, OND, CDER, FDA

4:05 p.m. Clarifying Questions

4:15 p.m. Summary of FDA Site Inspection of the  
DCRI Readjudication

**Ann Meeker-O'Connell**  
Acting Division Director  
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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**DRAFT AGENDA (cont.)**

**Day 2: June 6, 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>
8:25 a.m.	<b>GUEST SPEAKER PRESENTATION</b>  The 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>  The Rosiglitazone Risk Evaluation and Mitigation Strategy	<b>Joyce Weaver, PharmD, BCPS</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	<b>LT Justin A. Mathew, PharmD</b> Drug Use 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.	OPEN PUBLIC HEARING	
11:15 a.m.	COMMITTEE DISCUSSION	
12:00 p.m.	<b>LUNCH</b>	
1:00 p.m.	COMMITTEE DISCUSSION (CONT.)	
2:00 p.m.	<b>CHARGE TO THE COMMITTEE</b>	<b>Mary H. Parks, MD</b>
2:10 p.m.	COMMITTEE DISCUSSION/VOTE	
5:00 p.m.	<b>ADJOURNMENT</b>	