FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee
Gaithersburg Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, Maryland
***DRAFT* AGENDA**
July 30, 2007

The Committees will discuss the cardiovascular ischemic/thrombotic risks of the thiazolidinediones, with focus on rosiglitazone, as presented by the FDA and GlaxoSmithKline.

8:00 a.m.	Call to Order and Introductions	**Clifford Rosen, M.D**. (Acting) Committee Chair
8:05 a.m.	Conflict of Interest Statement	**LCDR Cathy A. Miller, M.P.H.** Designated Federal Official Endocrinologic and Metabolic Drugs Advisory Committee
8:10 a.m.	Introduction/Background	**Mary Parks, M.D.** Director, FDA/CDER Division of Metabolism and Endocrine Products

PRESENTATIONS:

Guest Speaker Presentation:

8:15 a.m.	Type II Diabetes Mellitus and Cardiovascular risks	**Robert E. Ratner, M.D.** Vice-President of Scientific Affairs MedStar Research Institute Washington, DC

GlaxoSmithKline Presentations:

8:35 a.m.	Introduction	**Ronald L. Krall, M.D.** Senior Vice President and Medical Officer GlaxoSmithKline
	Review of Data	**Murray W. Stewart, D.M., FRCP** Vice President, Clinical Development GlaxoSmithKline
	Conclusions	**Ronald L Krall, M.D.**
9:50 a.m.		**Clarifying Questions from the Committee**
10:05 a.m.		**Break**

FDA Presentations:

10:15	FDA Meta-Analysis	**Joy D. Mele, M.S**. Statistician, FDA/CDER Office of Biostatistics, Division of Biometrics II
	Overview of Large, Long-Term, Prospective Trials of Thiazolidinediones	**Karen M. Mahoney, M.D.** Medical Officer, FDA/CDER Division of Metabolism Endocrine Products

FDA Presentations (Continued):

	Bari-2D Trial	**David J. Gordon, M.D., Ph.D.** Division of Cardiovascular Diseases National Institute of Health National Heart, Lung and Blood Institute
	Observational Studies: Effect of Anti-Diabetic Agent Choice on Cardiovascular Morbidity and Mortality in Type II Diabetes Mellitus	**Kate Gelperin, M.D., M.P.H.** Medical Officer, FDA/CDER Office of Surveillance and Epidemiology, Division of Drug Risk Evaluation
	Assessment of health risks and Benefits associated with rosiglitazone	**David Graham, M.D., M.P.H.** Associate Director, FDA/CDER Associate Director for Science and Medicine, Office Surveillance and Epidemiology
	Conclusions and Summary	**Robert Meyer, M.D.** Director, FDA/CDER Office of New Drug Evaluation II **Gerald Dal Pan, M.D., M.H.S.** Director, FDA/CDER Office of Surveillance and Epidemiology
12:00		**Lunch**
1:00 - 2:30 p.m.		**Open Public Hearing**
2:30 p.m.		**Questions to the FDA/Discussion**
3:15 p.m.		**Break**
3:30 p.m.		**Questions to the Committee**
5:00 p.m.		**Adjourn**