FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Endocrinologic and Metabolic Drugs Advisory Committee Meeting
Hilton Hotel, Silver Spring, Maryland
April 1, 2009

AGENDA

The committee will discuss NDA 22-350, saxagliptin tablets, Bristol-Myers Squibb, proposed for treatment of hyperglycemia in adults with type 2 diabetes mellitus.

8:00 a.m.– 8:05 a.m.	Call to Order and Introductions	**Kenneth Burman, M.D.** Committee Chair Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC)
8:05 a.m. – 8:15 a.m.	Conflict of Interest Statement	**Paul Tran, R.Ph.** Designated Federal Official EMDAC
8:15 a.m. – 8:45 a.m.	Introduction/Background	**Hylton Joffe, M.D., M.M.Sc.** Diabetes Clinical Team Leader Center for Drug Evaluation and Research (CDER) Division of Metabolism and Endocrinology Products (DMEP)
8:45 a.m. – 10:00 a.m.	Sponsor Presentation	**Bristol-Myers Squibb**
	Introduction	**Joseph Lamendola, Ph.D.** Vice President Global Regulatory Sciences Bristol-Myers Squibb
	Overview of Development Program	**Robert Wolf, M.D., F.A.C.C.** Vice President Bristol-Myers Squibb
	Clinical Efficacy and Clinical Safety	**Roland Chen, M.D.** Group Director Cardiovascular/Metabolics Bristol-Myers Squibb
	Cardiovascular Safety Pharmacovigilence Plan Benefit-Risk	**Robert Wolf, M.D., F.A.C.C.** Vice President Bristol-Myers Squibb
	Assessment of Saxagliptin Post-approval	**Brian Daniels M.D.** Senior Vice President Global Development & Medical Affairs Bristol-Myers Squibb

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10:00 a.m. – 10:15 a.m.	Clarifying Questions From the Committee to Sponsor	
10:15 a.m. – 10:30 a.m.	**Break**	
10:30 a.m. – 11:45 a.m.	FDA Presentation	**Naomi Lowy, M.D.** Clinical Reviewer CDER, DMEP **Joy Mele, M.S.** Statistical Reviewer CDER, Office of Biostatistics
11:45 a.m. – 12:00 p.m.	Clarifying Questions From the Committee to FDA	
12:00 p.m. – 1:00 p.m.	**Lunch**	
1:00 p.m. – 2:00 p.m.	Open Public Hearing Session	
2:00 p.m. – 2:30 p.m.	Questions From Committee to Sponsor and FDA	
2:30 p.m. – 2:45 p.m.	**Break**	
2:45 p.m. – 5:00 p.m.	Discussion/Questions to the Committee	
5:00 p.m.	**Adjourn**	