

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Endocrinologic and Metabolic Drugs Advisory Committee
Holiday Inn Silver Spring
8777 Georgia Avenue, Silver Spring, MD**

***AGENDA*
September 9, 2005**

The committee will discuss new drug application (NDA) 21-865, proposed trade name Pargluva (muraglitazar) Tablets, 2.5 milligrams (mg) and 5 mg, Bristol-Myers Squibb, for the treatment of type II diabetes mellitus.

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8:00 Call to Order and Introductions **Nelson B. Watts, M.D.**
Committee Chair
Endocrinologic and Metabolic Drugs Advisory Committee

Conflict of Interest Statement **LCDR Cathy Groupe, B.S.N.**
Executive Secretary
Endocrinologic and Metabolic Drugs Advisory Committee

8:15 Welcome **David Orloff, M.D.**
Director
Division Metabolic and Endocrine Drug Products
FDA Center for Drug Evaluation and Research

Sponsor Presentation:

8:30 Introduction **Brian Daniels, M.D.**
Senior Vice President
Global Clinical Development
Bristol-Myers Squibb Company

Meeting the Needs for Type 2 DM **David M. Kendall M.D.**
University of Minnesota

Muraglitazar Overview **Fred Fiedorek M.D.**
Vice President
Global Clinical Research
Bristol-Myers Squibb Company

Non-Clinical Safety **Mark Dominick D.V.M., Ph.D.**
Distinguished Research Fellow
Drug Safety Evaluation

Clinical Efficacy **Cindy Rubin M.D.**
Group Director
Global Clinical Research
Bristol-Myers Squibb Company

Clinical Safety **Rene Belder M.D .**
Vice President
Global Clinical Research
Bristol-Myers Squibb Company

Clinical Plans,
Pharmacovigilance and
Benefit/Risk Conclusions **Fred Fiedorek M.D.**

10:00 **Committee Discussion**

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AGENDA (Continued)
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10:30		Break
	<u>FDA Review Division Presentation:</u>	
10:45	Clinical Review	Julie Golden, M.D. Medical Officer Division of Metabolic and Endocrine Drug Products FDA Center for Drug Evaluation and Research
11:15	Pharmacology/Toxicology Review	Jeri El Hage, Ph.D. Pharmacologist Division of Metabolic and Endocrine Drug Products FDA Center for Drug Evaluation and Research
11:45		Committee Discussion
12:00		Lunch
1:00		Open Public Hearing
3:00		Break
3:15		Committee Discussion and Questions
5:00		Adjournment