FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Endocrinologic and Metabolic Drugs Advisory Committee Meeting
Hilton Silver Spring, 8727 Colesville Rd., Silver Spring, Maryland
***DRAFT* AGENDA**
June 13, 2007

The committee will discuss the efficacy and safety of new drug application (NDA) 21–888, proposed tradename Zimulti (rimonabant), 20 milligrams tablets, Sanofi-Aventis, as an adjunct to diet and exercise for obesity management in patients with a body mass index equal to or greater than 30 kilograms (kg) per square meter, or a body mass index equal to or greater than27 kg per square meter if accompanied by at least one cardiovascular risk factor.

8:00 a.m.	Call to Order and Introductions	**Clifford Rosen, M.D.** (Acting) Committee Chair
8:10 a.m.	Conflict of Interest Statement	**LCDR Cathy A. Miller, M.P.H.** Designated Federal Official Endocrinologic and Metabolic Drugs Advisory Committee
8:15 a.m.	Introduction/Background	**Eric G. Colman, M.D.** Deputy Director, FDA/CDER Division of Metabolic and Endocrine Products

PRESENTATIONS:

8:30 a.m.	**Guest Speaker Presentation** ***Title TBD***	**Kelly Posner, Ph.D.** Department of Child Psychiatry New York State Psychiatric Institute New York, NY
8:45 a.m.	**Sponsor Presentations - Sanofi-Aventis:**	
	Introduction	**Mark Moyer, M.D.** Vice President, Regulatory Development, Sanofi-Aventis
	Mechanism of Action	**Kenneth P. Mackie, M.D.** Linda and Jack Gill Chair of Neuroscience, Professor of Psychology, Department of Psychological & Brain Sciences Indiana University
	Medical Need and the Clinical Efficacy of Rimonabant	**Pierre Rosenzweig, M.D.** Vice President, International Clinical Development Internal Medicine, Sanofi-Aventis
	Clinical Safety of Rimonabant	**Paul Chew, M.D.** Vice President, International Clinical Development Metabolism, Diabetes, and Thrombosis, Sanofi-Aventis
	Proposed Risk Management Plan	**Antonio Tatarani, M.D.** Vice President, Medical Director Medical Affairs, Sanofi-Aventis
	Benefit/Risk of Rimonabant	**Louis Aronne, M.D.** Clinical Professor of Medicine Weill Medical College of Cornell University

10:45 a.m.		**Clarifying Questions from the Committee**
11:00 a.m.		**Break**
FDA Presentations:		
11:15 a.m.	Preclinical Evaluation of Rimonabant	**Karen Davis-Bruno, Ph.D.** Pharmacologist, FDA/CDER Division of Metabolic and Endocrine Drug Products
11:45 a.m.		**Clarifying Questions from the Committee**
12:00 p.m.		**Lunch**
1:00 p.m.		**Open Public Hearing**
FDA Presentations (Continued):		
1:15 p.m.	Clinical Efficacy and Safety of Rimonabant	**Amy Egan, M.D., M.P.H.** Medical Officer, FDA/CDER Division of Metabolic and Endocrine Drug Products
2:15 p.m.		**Break**
2:30 p.m.		**Committee Discussion and Questions**
5:00 p.m.		**Adjourn**