

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

***Endocrinologic and Metabolic Drugs Advisory Committee Meeting
September 8, 2004***

Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave, Bethesda Maryland

AGENDA

***The FDA draft guidance document entitled:
“GUIDANCE FOR THE CLINICAL EVALUATION OF WEIGHT-CONTROL DRUGS”
(dated 9/24/1996)***

8:00 a.m.	Call to Order and Introductions	Glenn Braunstein, M.D. Acting Chair, Endocrinologic and Metabolic Drugs Advisory Committee, EMDAC
	Conflict of Interest Statement	LCDR Dornette Spell-LeSane, M.H.A., NP-C Executive Secretary, EMDAC
	Welcome and Introductory Comments	David Orloff, M.D. Director Division of Metabolic and Endocrine Drug Products (DMEDP), FDA
<hr/>		
8:15	FDA Presentation	
	<i>The Regulatory History of Weight-Loss Drugs</i>	Eric Colman, M.D. Medical Team Leader DMEDP, FDA
8:45	<i>The Epidemiology of Overweight and Obesity</i>	Katherine Flegal, Ph.D. Senior Research Scientist National Center for Health Statistics
9:15	<i>Current Status of Weight-Loss Drugs</i>	Frank Greenway, M.D. Medical Professor, Director Pennington Biomedical Research Center

***Endocrinologic and Metabolic Drugs Advisory Committee Meeting
September 8, 2004***

AGENDA

cont.

- 9:45 *Patterns of Weight-Loss Drug Use* Laura A. Governale, Pharm.D., MBA
Drug Utilization Specialist, Team Leader
Division of Surveillance
Research and Communication Support
Office of Drug Safety (ODS), FDA
- 10:15 Break
- 10:30 **FDA Presentation, cont.**
- Role of Drugs in the Treatment
of Obesity: Current and Future* Richard L. Atkinson, M.D.
Obesity Research Center Director, Obetech
- 11:00 Open Public Hearing
- The 1996 FDA Draft Guidance Document* David Orloff, M.D.
Director, DMEDP
- Charge to the Committee David Orloff, M.D.
Director, DMEDP
- 12:30 Lunch
- 1:15 Committee Discussion/Questions
- 4:30 Adjourn