

**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

DRAFT AGENDA

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

***The FDA draft guidance document entitled: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

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>	TBA
9:15	<i>Current Status of Weight-Loss Drugs</i>	TBA

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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)

10:15 Break

10:30 **FDA Presentation Continued**

The 1996 FDA Draft Guidance Document

David Orloff, M.D.
Director, DMEDP

11:00 Open Public Hearing

12:00 **Lunch**

1:00 Questions from the Committee

2:00 Charge to the Committee

David Orloff, M.D.
Director, DMEDP

2:15 Committee Discussion

3:15 Break

3:30 Committee Discussion

5:00 Adjourn