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

Endocrinologic and Metabolic Drugs Advisory Committee Meeting
October 7, 2003

Holiday Inn, Versailles Ballroom, Bethesda, MD

DRAFT AGENDA

8:00 a.m.	Call to Order and Introductions	Michael McClung, M.D. Acting Chair, Endocrinologic and Metabolic Drugs Advisory Committee, EMDAC
	Conflict of Interest Statement	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, FDA

Women's Health Initiative Study Results: Implications for the use of hormone therapy with estrogen/progestin as a second-line drug for the prevention and treatment of postmenopausal osteoporosis in women.

8:15 Open Public Hearing

9:15 **FDA Presentation**

Criteria of effectiveness and safety in the evaluation of osteoporosis drug products	Eric Colman, M.D. Division of Endocrinologic and Metabolic Drugs, FDA

9:30 **WHI Presentations**

Overview of the Women's Health Initiative (WHI)	Jacques Rossouw, MD NHLBI
	Marcia Stefanick, Ph.D. Stanford Center for research in Disease Prevention

WHI Presentations Cont.

	Interpretation of breast cancer results	Rowan Chelebowski, M.D. WHI at Harbor-UCLA Garnet Anderson, Ph.D Fred Hutchinson Cancer Research Center

10:15 Break

10:30 **WHI Presentations Cont.**

	Osteoporosis	Jane Cauley, DrPH University of Pittsburgh Garnet Anderson, Ph.D.
	Future Clinical Trials	Jacques Rossouw, MD

11:30 Questions from the Committee

12:00 Lunch

1:00 **Presentation by Wyeth Pharmaceuticals**

2:00 Questions from the committee

2:30	**FDA Presentation**	Bruce Stadel, M.D., MPH Eric Colman, M.D.
3:00	Break	
3:15	Charge to the Committee	David Orloff, M.D.
3:30	Committee Discussion	

5:00 Adjourn