Food and Drug Administration
Center for Drug Evaluation and Research

Endocrinologic and Metabolic Drugs Advisory Committee
Hilton Silver Spring, 8120 Wisconsin Avenue, Bethesda, MD

Agenda
September 25, 2002
Clinical Trials for New Osteoporosis Treatments

8:00 Call to Order and Introductions: Glenn Braunstein, M.D., Chair
Meeting Statement: Kathleen Reedy, Executive Secretary
Welcome: David G. Orloff, M.D., Director
Division of Metabolic and Endocrine Drug Products

8:15: The U. S. and European Osteoporosis Guidance Documents
A. History of US Guidance: Eric Colman, M.D. (FDA)
B. Evolution of the European Guidance: Eric Abadie, M.D.
C. Rationale and durability of US Guidance: Henry G. Bone III, M.D.

9:15: Preclinical Models of Drug Efficacy and Skeletal Toxicity
A: Gideon A. Rodan, M.D., Ph.D.
B: Rene Rizzoli, M.D.
C: Charles H. Turner, Ph.D.

10:30: Break

10:45: Measures of Clinical Efficacy
A. **Measurement of Bone Mineral Density and Vertebral Fractures:** Kenneth G. Faulkner, Ph.D.
B. **Relationship of Drug Associated Change in Bone Mineral Density to Fracture Risk:** Marc C. Hochberg, M.D., M.P.H.

11:45: Open Public Hearing

12:45: Lunch

1:30: The Size, Scope and Implications of Placebo vs. Active-Control Trials: Steven R. Cummings, M.D.

2:15: Charge: David G. Orloff, M.D

2:30: Discussion

5:30: Adjourn