

**Food and Drug Administration  
Center for Drug Evaluation and Research**

**Endocrinologic and Metabolic Drugs Advisory Committee  
Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD**

**Agenda  
July 27, 2001**

**NDA 21-318, Fortéo™ (teriparatide injection, rDNA origin) Eli Lilly and Company**

**8:00 Call to Order and Introductions:** Mark E. Molitch, M.D., Acting Chair  
**Meeting Statement:** Kathleen Reedy, Executive Secretary

**8:15 Welcome and Introduction:** David G. Orloff, M.D., Director  
Division of Metabolic and Endocrine Drug Products

**8:30 Eli Lilly and Company Presentation**

Introduction: Jennifer L. Stotka, MD, Executive Director,  
US Regulatory Affairs, Eli Lilly and Company  
History, Mechanism of Action and Clinical Need: Robert Lindsay, MD, PhD  
Professor of Clinical Medicine, Columbia University  
Chief of Internal Medicine, Helen Hayes Hospital  
Nonclinical Overview: John L. Vahle, DVM, PhD, Senior Research Pathologist,  
Toxicology, Eli Lilly and Company  
Clinical Efficacy: Bruce H. Mitlak, MD, Medical Director, Fortéo Product Team  
Eli Lilly and Company  
Clinical Safety: Gregory A. Gaich, MD, Senior Research Clinical Physician,  
Fortéo Product Team, Eli Lilly and Company  
Summary and Conclusions: Bruce H. Mitlak, MD

**10:00 Break**

**10:15 FDA Presentation:** Division of Metabolic and Endocrine Drug Products  
Preclinical Studies: Gemma Kuijpers, Ph.D.  
Efficacy: Bruce S. Schneider, M.D.  
Safety: Bruce V. Stadel, M.D., M.P.H.

**11:15 Open Public Hearing**

**11:45 Lunch**

**1:00 Charge to the Committee:** David G. Orloff, M.D., Director  
Division of Metabolic and Endocrine Drug Products  
**Discussion and Questions**

**Break**

**4:30 Summary and Review**

**5:00 Adjourn**

