Joint Public Meeting on Equivalence of Levothyroxine Sodium Products
Co-sponsored with the FDA by the American Thyroid Association, The Endocrine Society and the American Association of Clinical Endocrinologists

Monday, May 23, 2005

National Transportation Safety Board
L'Enfant Plaza
Washington, DC

AGENDA AND SCHEDULE

8:30 – 8:45 am	Welcoming Remarks: Steve K. Galson, M.D., MPH Acting Director, Center for Drug Evaluation and Research (CDER)/FDA Paul W. Ladenson, M.D. Johns Hopkins University School of Medicine

Session I: Background: Clinical Issues and New Drug Applications for Levothyroxine

8:45 – 9:15 am	Levothyroxine Sodium: A Widely Employed Narrow Therapeutic Range Drug Paul W. Ladenson, M.D. Johns Hopkins University, School of Medicine
9:15 – 9:30 am	Overview of FDA General Regulatory Requirements and Methods for Demonstration of Therapeutic Equivalence Dale P. Conner, Pharm.D., CDER/FDA
9:30 – 9:45 am	Manufacturing Standards Eric P. Duffy, PhD, CDER/FDA
9:45 – 10:00 am	Bioavailability/Bioequivalence Studies in Evaluation of New Levothyroxine Products Henry J. Malinowski, PhD, CDER/FDA
10:00 – 10:15 am	Report of Recently Approved Products' Performance in Bioequivalence Testing Barbara Davit, PhD, CDER/FDA
10:15 – 10:35 am	Limitations of Current Bioequivalence Standards James Hennessey, M.D. Brown Medical School
10:35 – 10:50 am	**BREAK**
10:50 – 11:50 am	Public Comment Period - Questions and Panel Discussion

11:50 am-12:50 pm **LUNCH**

12:50 – 1:20 pm Public Comment Period – Questions and Panel Discussion (Continued)

Session II: Approach to Comparing Levothyroxine Products: Serum Thyrotropin (TSH) Concentration as a Pharmacodynamic Measure of Thyroxine Bioequivalence and Study Design Considerations

1:20 – 1:40 pm Rationale for TSH as a Marker of Thyroid Hormone Tissue Effects
E. Chester Ridgway, M.D.
University of Colorado, School of Medicine

1:40 – 1:55 pm Levothyroxine or TSH for Determination of Bioequivalence: Study Design Considerations (including study populations and controls, crossover vs. parallel group, sample size, etc.)
Steven I. Sherman, M.D.
University of Texas, Anderson Cancer Center

1:55 – 2:15 pm FDA Perspective on Pharmacodynamic Bioequivalence Measures, Methodological and Regulatory Considerations and Study Design Issues in TSH-based BE Studies
Robert Lionberger, PhD, CDER/FDA

2:15 – 3:15 pm Public Comment Period - Questions and Panel Discussion

Session III: Summary of Issues/Next Steps

3:15 – 3:35 pm Society concerns regarding current U.S. Prescribing and Dispensing Practices
Leonard Wartofsky, MD
Uniformed Services, University of the Health Sciences

3:35 – 3:50 pm FDA Summary
David G. Orloff, M.D., CDER/FDA

3:50 – 4:05 pm **BREAK**

4:05 – 5:05 pm Public Comment Period - Questions and Panel Discussion

5:05 – 5:30 pm Closing Remarks:
David Orloff, M.D., CDER/FDA

Paul Ladenson, M.D.
Johns Hopkins University
School of Medicine