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
490 L'Enfant Plaza, SW
Washington, DC 20594

AGENDA AND SCHEDULE

8:30 – 8:45 am	Welcoming Remarks - Steve Galson, M.D. and Society Representatives

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, MD
9:15 – 9:30 am	Overview of FDA General Regulatory Requirements and Methods for Demonstration of Therapeutic Equivalence Dale P. Conner, Pharm.D.
9:30 – 9:45 am	Manufacturing Standards Eric P. Duffy, PhD
9:45 – 10:00 am	Bioavailability/Bioequivalence Studies in Evaluation of New Levothyroxine Products Henry J. Malinowski, PhD
10:00 – 10:15 am	Report of Recently Approved Products' Performance in Bioequivalence Testing Barbara Davit, PharmD
10:15 – 10:35 am	Limitations of Current Bioequivalence Standards James Hennessey, M.D.
10:35 – 10:50 am	**BREAK**
10:50 – 11:20 am	Questions and Panel Discussion
11:20 – 11:50 am	Public Comment Period
11:50 am-12:50 pm	**LUNCH**

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

12:50 – 1:10 pm	Rationale for TSH as a Marker of Thyroid Hormone Tissue Effects E. Chester Ridgway, M.D.
1:10 – 1:25 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.
1:25 – 1:45 pm	FDA Perspective on Pharmacodynamic Bioequivalence Measures, Methodological and Regulatory Considerations and Study Design Issues in TSH-based BE Studies Robert Lionberger, PhD
1:45 – 2:15 pm	Questions and Panel Discussion
2:15 – 2:45 pm	Public Comment Period

Session III: Summary of Issues/Next Steps

2:45 – 3:05 pm	Society concerns regarding current U.S. Prescribing and Dispensing Practices Leonard Wartofsky, MD
3:05 - 3:20 pm	FDA Summary David G. Orloff, M.D.
3:20 – 3:35 pm	**BREAK**
3:35 – 4:05 pm	Questions and Panel discussion
4:05 - 4:35 pm	Public Comment
4:35 – 5:00 pm	Closing Remarks - David Orloff, M.D. and Society Representatives