

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

**JOINT MEETING BETWEEN  
THE ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE (EMDAC)  
AND  
THE ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)**

**October 4, 2006**  
Gaithersburg Hilton, The Ballrooms  
620 Perry Parkway  
Gaithersburg, MD

**AGENDA**

- 8:00 **Call to Order and Introduction of Committees** **Nelson B. Watts, M.D.**  
Chairman, Endocrinologic and Metabolic Drugs  
Advisory Committee (EMDAC)
- Conflict of Interest Statement** **Victoria Ferretti-Aceto, Pharm.D.**  
(Acting) Designated Federal Officer, EMDAC
- FDA PRESENTATIONS**
- 8:10 **Introduction to Meeting** **Mary H. Parks, M.D.**  
Director, Division of Metabolism and  
Endocrinology Products/CDER/FDA
- 8:15 **Regulatory History of Levothyroxine Products** **Jane A. Axelrad, J.D.**  
Associate Director for Regulatory  
Policy/CDER/FDA
- 8:30 **Clinical Perspectives on Levothyroxine Products** **Mary H. Parks, M.D.**  
Director, Division of Metabolism and  
Endocrinology Products/CDER/FDA
- 8:45 **Stability of Levothyroxine Sodium Products** **Eric P. Duffy, Ph.D.**  
Director, Division of Post-Marketing  
Evaluation/CDER/FDA
- 9:30 *Questions from the Committee*
- 9:45 **Break**

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

**JOINT MEETING BETWEEN  
THE ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE (EMDAC)  
AND  
THE ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE (ACPS)**

**October 4, 2006**  
Gaithersburg Hilton, The Ballrooms  
620 Perry Parkway  
Gaithersburg, MD

**AGENDA**

**INDUSTRY PRESENTATIONS**

- |       |  |   |
|-------|--|---|
| 10:00 | <b>Levothyroxine Sodium</b>  | <b>John Leonard, M.D.</b><br>Vice President, Global Pharmaceutical Research<br>and Development, Abbott Laboratories |
| 10:20 | <b>Global Experience: Levothyroxine Quality<br/>and Safety</b>   | <b>Bonnie Southorn, Ph.D.</b><br>Director, Core Technical Documentation and<br>Submissions, Genpharm Inc.           |
| 10:40 | <b>Levothyroxine Sodium Tablets:<br/>A Manufacturer's Perspective</b>  | <b>Ronald Steinlauf</b><br>Vice President<br>Jerome Stevens Pharmaceuticals, Inc.                                   |
| 11:00 | <b>Mylan's Unique Formulation and Process for the<br/>Consistent Production of a Potent, Uniform and<br/>Stable Levothyroxine Sodium Product</b> | <b>David Wargo, R.Ph., Ph.D.</b><br>Senior Director, Product Development,<br>Mylan Pharmaceuticals, Inc.            |
| 11:20 | <i>Questions from the Committee</i>  |   |
| 11:40 | <b>Lunch</b>   |   |
| 1:00  | <b>Open Public Hearing</b>   |   |
| 2:00  | <b>FDA Summary of Issues</b>   | <b>Mary H. Parks, M.D.</b><br>Director, Division of Metabolism and Endocrine<br>Drug Products/CDER/FDA              |
| 2:10  | <i>Discussions</i>   |   |
| 3:10  | <b>Break</b>   |   |
| 3:25  | <i>Questions to the Committee and Recommendations</i>  |   |
| 5:00  | <b>Adjourn</b>   |   |