

Food and Drug Administration
Center for Drug Evaluation and Research

Arthritis Advisory Committee
Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD

Agenda
July 29, 2002
Pain

- 8:00** **Call to Order and Introductions:** Gary
S. Firestein, M.D., Chair
- Meeting Statement:** Kathleen Reedy, Executive Secretary
Welcome: Lee S. Simon, M.D.,
Director, Division of Analgesic,
AntiInflammatory and Ophthalmologic Drug
Products
- 8:15 Introduction:** James Witter, M.D., Ph.D.
- 8:30 1992 Guidance:** Christina Fang, M.D.
Sharon Hertz, M.D.
- 9:00 Basic Science:** Clifford J. Woolf, MD, PhD
- 9:30 Discussion Points: #1, 2**
- 10:00 Break**
- 10:15 Claim Structure:** Lee S. Simon, M.D.
- 10:45 Discussion Points #3, 4**
- 11:15 Back Pain, Chronic Issues:** David Borenstein, M.D.
- 11:45 Discussion Point #5**
- 12:00 Lunch**
- 1:00 Open Public Hearing**
- 3:00 Break**
- 3:15 Introduction:** James Witter, M.D., Ph.D.
- 3:20 Tolerance and Toxicity:** Nathaniel P. Katz, MD
- 3:50 Landmark vs. AUC:** Laura Lu, Ph.D.
- 4:00 Open Discussion of Points: # 1, 2, 3, 4 and 5**
- 5:00 Adjourn**

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July 30, 2002
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| 8:00 | Call to Order and Introductions: | Gary S. Firestein, M.D., Chair |
| | Meeting Statement: | Kathleen Reedy, Executive Secretary |
| | Welcome: | Lee S. Simon, M.D., Director, DAAODP |
| | Comments, Charge: | Lawrence Goldkind, M.D.,
Deputy Director, DAAODP |
| 8:15 | ABC Metrics of Acute Pain: | James Witter, M.D., Ph.D. |
| 8:45 | Dosing Intervals: | Lawrence Goldkind, M.D. |
| 9:15 | Safety Databases for Acute Analgesics: | Lourdes Villalba, M. D. |
| 9:45 | Discussion Points # 1, 2, 3 | |
| 10:30 | Break | |
| 10:45 | Open Public Hearing | |
| 11:45 | Lunch | |
| 1:00 | Responder Index, a model: | Vibeke Strand, MD |
| 1:30 | Discussion Point # 4 | |
| 3:00 | Summary: | Lee S. Simon, M.D., Director, DAAODP |
| 3:30 | Adjourn | |