

REVISED

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**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

**January 30-31, 2001
Holiday inn, 8120 Wisconsin Ave., Bethesda, Maryland**

AGENDA

Wednesday, January 31

- 9 AM** Call to order; introductions; announcements
- 9:15** **Session 2 — OPEN Session**
SmithKline Beecham's LYMERix™ Lyme Disease Vaccine Safety Update
- 9:15 introduction Dr. Karen Midthun, FDA
- 9:25 FDA Presentation on Pre-licensure Safety
Data and Post Marketing Commitments Dr. Patricia Rohan, FDA
- 9:40 Q&A - Clarifications of FDA's Presentation
- 9:50 Sponsor's Presentation on Pre-licensure Safety Data SmithKline Beecham
- 10:20 Q&A – Clarifications of Sponsor's Presentation
- 10:30** **Break**
- 10:50 Sponsor's Presentation on Phase 4 Study SmithKline Beecham
- 11:10 Sponsor's Presentation on Additional Post-marketing Data Smith Kline Beecham
- 11:20 Q&A – Clarifications of Sponsor's Presentations
- 11:30 FDA Presentation on VAERS Data Dr. Robert Ball, FDA
- 11:50 Q&A – Clarifications of FDA's Presentation
- 12 noon** **Lunch**
- 1:00** **Open Public Hearing**
- 3:15** **Committee Discussion**
- 5:30** **Adjournment**

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