

AGENDA

TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE

Crowne Plaza, 8777 Georgia Avenue, Silver Spring, MD
December 15, 2006

Friday, December 15, 2006

8:00 a.m. Administrative Remarks, TSEAC Executive Secretary

8:05 a.m. Opening Remarks, Glen Telling, Ph.D. Chairperson, TSEAC

8:10 a.m. Committee Update

- Status of FDA's initiative on communication of the potential exposure to vCJD risk from an investigational product, plasma derived Factor XI that was manufactured from UK donor plasma (15') (M. Weinstein, Ph.D., FDA)

8:25 a.m. Topic I. FDA's risk assessment for potential exposure to vCJD in human plasma-derived antihemophilic factor (FVIII) products and communication materials.

A. Introduction: FDA risk management strategy for potential exposure to vCJD in plasma derivatives (D. Scott, M.D., FDA) (10')

B. Risk assessment and interpretation (S. Anderson, Ph.D., FDA) (40')

C. Overall risk communication approach
(M. Weinstein, Ph.D., FDA) (15')

D. Patient advocate perspectives (40')

- i. National Hemophilia Foundation (Val Bias) (5')
- ii. Hemophilia Federation of America (Janice Hamilton) (5')
- iii. Committee of Ten Thousand (Richard Colvin, M.D., Ph.D.) (5')
- iv. World Federation of Hemophilia (Mark Skinner) (5')

10:10 a.m. Break

10:25 a.m. Open Public Hearing

10:55 a.m. FDA Questions for the Committee

11:05 p.m. Open Committee Discussion and Recommendations

12:00 p.m. Lunch

- 1:00 p.m. Topic II. Levels of TSE clearance in the manufacture of plasma-derived FVIII
- A. Summary of 18 September 2006 TSEAC discussion (D. Scott, M.D., FDA) (15')
 - B. Updated information from manufacturers (T. Kreil, Ph.D., PPTA Baxter Bioscience) (20')
- 1:35 p.m. Open Public Hearing
- 2:05 p.m. FDA Questions for the Committee (10')
- 2:15 p.m. Discussion (45')
- 3:00 p.m. Adjourn