

**FOOD AND DRUG ADMINISTRATION**

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES  
ADVISORY COMMITTEE**

Holiday Inn, Ballroom 2  
2 Montgomery Village Avenue  
Gaithersburg, MD 20879  
February 20, 2003

**AGENDA**

Thursday, February 20, 2003

**OPEN SESSION**

- 8:00 a.m. Administrative Remarks,  
William Freas, Ph.D., Executive Secretary
- 8:10 a.m. Presentation of Plaques to Former Members  
Lester Crawford, D.V.M., Ph.D.  
Deputy Commissioner, FDA
- 8:20 a.m. Opening Remarks  
Suzette Priola, Ph.D., Acting Chairperson
- 8:25 a.m. Update #1: Implementation vCJD Guidance - Blood Supply  
after Implementation of European Donor Deferral
- Overview of Blood Supply Monitoring  
Alan Williams, Director, Division of Blood Applications,  
OBRR, FDA
- Blood Supply Monitoring  
DHHS: Capt. Lawrence McMurtry  
Acting Executive Secretary, DHHS Advisory  
Committee on Blood Safety and Availability  
ABC: Celso Bianco, M.D.  
Executive Vice President, ABC  
ARC: Peter L. Page, M.D.  
Senior Medical Officer, ARCBS-BHQ  
NYBC: Robert Jones, M.D.  
President, New York Blood Center  
AABB: Kay Gregory, MS, MT (ASCP)SBB  
Director Regulatory Affairs, AABB

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES  
ADVISORY COMMITTEE AGENDA**

**Thursday, February 20, 2003 (Continued)**

- 9:55 a.m. Questions for Presenters
- 10:10a.m. **OPEN PUBLIC HEARING**
- 10:30 a.m. BREAK
- 10:45 a.m. Update #2: BSE Epidemiology and Food Chain Controls  
David Asher, M.D., OBRR, FDA
- 11:15 a.m. Topic #1: Consideration of Labeling Claims for Transmissible  
Spongiform Encephalopathy (TSE) Agent Clearance in Plasma  
Derivatives
- Introduction  
Dorothy Scott, M.D., OBRR, FDA
- Virus Removal from Blood Products: Validation, Label Claims  
and Possible Paradigm for Removal of TSE Agents  
Mahmood Farshid, Ph.D., OBRR, FDA
- TSE Agent Clearance Issues  
Dorothy Scott, M.D., OBRR, FDA
- Risk Analysis for TSE and Plasma Derivatives  
Steven Anderson, Ph.D., OBE, FDA
- European Perspective on TSE Agent Clearance in Plasma  
Derivatives  
Sol Ruiz, Ph.D., Division of Biologicals and  
Biotechnology, Spanish Medicines Agency
- 12:45 p.m. LUNCH
- 1:45 p.m. Committee Discussion
- 2:05 p.m. TSE Clearance Studies – Scientific Presentations from Industry  
Henry Baron, MD  
Senior Director – Prion Research, Aventis Behring  
(Speaking on behalf of the Plasma Protein Therapeutics  
Association)

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES  
ADVISORY COMMITTEE AGENDA**

**Thursday, February 20, 2003 (Continued)**

- |           |                               |
|-----------|-------------------------------|
| 3:35 p.m. | <b>OPEN PUBLIC HEARING</b>    |
| 4:15 p.m. | <b>BREAK</b>                  |
| 4:30 p.m. | Questions to the Committee    |
| 4:35 p.m. | Committee Discussion and Vote |
| 5:35 p.m. | <b>ADJOURN</b>                |

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE  
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FEBRUARY 20, 2003**

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