

**FOOD AND DRUG ADMINISTRATION**

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES  
ADVISORY COMMITTEE**

Hilton Hotel  
8727 Colesville Road  
Silver Spring, MD 20910

**AGENDA**

Thursday, October 14, 2004

- 8:00 a.m. Administrative Remarks,  
William Freas, PhD, Executive Secretary
- 8:10 a.m. Opening Remarks  
Suzette Priola, PhD, Chairperson  
Introduction  
Jesse L. Goodman, MD, MPH,  
Director, Center for Biologics Evaluation and Research  
Presentation of Plaques to Retiring Committee Members  
Jesse Goodman, MD, MPH
- 8:20 a.m. Informational Presentation #1: USDA BSE Licensed Tests and  
Enhanced Surveillance Program, Lawrence Elsken, DVM, USDA  
  
Informational Presentation #2: USDA Review of Worldwide BSE  
Situation and USDA Responses, Lisa Ferguson, DVM, USDA  
  
Informational Presentation #3: Update on Animal Feed  
Rulemaking, Burt Pritchett, DVM, CVM
- 9:05 a.m. Questions for Presenters
- 9:15 a.m. **OPEN PUBLIC HEARING**
- 10:05 Informational Presentation #4: Labeling Claims for TSE  
Clearance Studies for Plasma Derivative Products,  
Dorothy Scott, MD, OBRR, FDA
- 10:15 Informational Presentation # 5: Industry-Wide Data on TSE  
Clearance from Plasma Products, Henry Baron, MD, Senior  
Director- Prion Research, ZLB Behring (Speaking on behalf of the  
Plasma Protein Therapeutics Association)
- 10:30 **BREAK**

## **TSEAC AGENDA (page 2)**

- 10:50 a.m.                    **Topic – Presumptive Transfusion Transmissions of Variant CJD (vCJD): Consideration of Current FDA-Recommended Safeguards**
- A. FDA Introduction, David Asher, MD, OBRR/FDA
  - B. Presumptive Transfusion Transmission of vCJD (review of CJD and vCJD: UK and EU epidemiology, case reports, surveillance and projections, potential public health implications, and responses), Professor Robert G. Will, MD, UK CJD Surveillance Unit
  - C. Comparison of the Transfusion Risk for CJD vs. vCJD, Steven Anderson, PhD, OBE/FDA
  - D. Leukoreduction and Its Failure to Remove Most Infectivity from Blood, Luisa Gregori, PhD, VA Medical Center
- 12:10 p.m.                    Questions for Speakers
- 12:25                         **LUNCH**
- 1:25                            E. Changes in Canadian CJD/vCJD Blood Safety Policies, Peter Ganz, PhD, HealthCanada
- F. Current Safeguards for Blood Products Recommended by FDA, Dorothy Scott, MD, OBRR/CBER
- G. Possible Effects of Prior CJD-Related Blood Donor Deferrals on Blood Supply, Alan Williams, PhD, OBRR/CBER
- 2:30                            Questions for Speakers
- 2:45                            **OPEN PUBLIC HEARING**
- 3:15                            **BREAK**
- 3:35                            Questions to the Committee
- 3:45                            Committee Discussion and Vote
- 5:00 p.m.                    **ADJOURN**