

AGENDA

FOOD AND DRUG ADMINISTRATION

Joint meeting of the
**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE**
and the
BLOOD PRODUCTS ADVISORY COMMITTEE

Holiday Inn Select
Versailles Ballrooms I & II
Bethesda, Maryland 20814
January 17, 2002

Thursday January 17, 2002, OPEN SESSION

- 8:00 a.m. Administrative Remarks,
William Freas, PhD, Executive Secretary
- 8:05 Presentation of Certificates
Jesse Goodman, M.D., Deputy Director (Medicine) CBER
- 8:10 Opening remarks
David Bolton, PhD, Committee Chairman
- Committee Update
- 8:15 Revised FDA Guidance on Preventive Measures to Reduce the
Possible Risk of Transmission of CJD and vCJD by Blood and
Blood Products: Final Guidance
Dorothy Scott, MD (OBRR, CBER, FDA)
- 8:45 **Open Public Hearing**
- Committee Update
- 9:15 PPTA presentations on clearance of spiked TSE infectivity and
protease-resistant prion proteins by plasma processing
Christopher Healey, JD, PPTA
Douglas Lee, PhD, Bayer Corporation,
Martin Vey, PhD, Aventis Behring
Thomas Kreil, PhD, Baxter Bioscience
- 10:15 Break

Thursday January 17, 2002, OPEN SESSION (Continued)

Topic #1: Effectiveness of measures taken to protect humans from food-borne exposure to the BSE agent in countries with BSE: Implications for vCJD risk and blood safety

- 10:30 Introduction, background, charge and questions
David M. Asher, MD (OBRR, CBER, FDA)
- 10:50 Variant CJD in the UK: Update and review of recent epidemiological studies
Hester Ward, MD (CJD Surveillance Unit and Western General Hospital, Edinburgh, UK)
- 11:30 BSE and human food chain protective measures in the UK
Peter Soul, DVM (DEFRA, London, UK)
- 12:10 Efforts and needs for global control of BSE and vCJD: A view from the WHO
Maura Ricketts, MD (WHO, Geneva, Switzerland)
- 12:40 Lunch break
- 1:40 **Open Public Hearing**
- 2:10 Committee discussion
- 2:30 Questions to the Committees
- 3:00 Committee update
- Harvard BSE Risk Assessment: Summary and update
George M. Gray, PhD and Joshua Cohen, PhD (Center for Risk Analysis, Harvard School of Public Health, Boston)
- 4:00 Questions from the Committees to presenters
- 4:30 Adjourn