

DRAFT AGENDA (revised 01/10/02)

FOOD AND DRUG ADMINISTRATION

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

Holiday Inn
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

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
 To be assigned (Aventis Behring)
 Douglas Lee, PhD (Bayer Corporation, Research Triangle
 Park, NC)
 To be assigned (PPTA)

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