**AGENDA**

# Food and Drug Administration
# Transmissible Spongiform Encephalopathies
# Advisory Committee
### Monday, October 31, 2005
### Holiday Inn Bethesda

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| 8:00 a.m. | Administrative Remarks | William Freas, PhD, CBER, Executive Secretary TSEAC |
| 8:10 | Recognition of Committee Service | Jesse L. Goodman, MD, MPH Director, CBER |
| 8:15 | Opening Remarks | Suzette Priola, PhD, NIAID, NIH, Chairperson TSEAC |

**Informational Presentations**

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| 8:20 | Update on US and worldwide BSE status | Lisa Ferguson, DVM, APHIS, USDA |
| 8:35 | Scientific issues in evaluating products intended to decontaminate surgical instruments exposed to TSE agents: discussions of a recent FDA Device Panel | Sheila Murphey, MD, CDRH |

## Topic 1: Progress Report on FDA's Risk Assessment for Potential Exposure to Variant Creutzfeldt-Jakob Disease in Human Plasma-Derived Antihemophilic Factor (FVIII) Products

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| 8:50 | Introduction and Questions to the Committee | Dorothy Scott, MD, OBRR, CBER |
| 9:00 | Variant CJD risk associated with human plasma derivatives: Introduction and overview of risk model | Steven Anderson, PhD, OBE, CBER |
| 9:30 | Update on vCJD in UK and other countries: estimates of prevalence | Azra C. Ghani, PhD, London School of Hygiene and Tropical Medicine<br>Richard Knight, MD UK, Director, CJD Surveillance Unit, Edinburgh |
| 10:30 | Break | |
| 10:50 | Modeling risk of vCJD in US donors – residual risk and efficiency of donor deferral | Alan Williams, PhD, OBRR, CBER |
| 11:05 | VCJD infectivity of plasma – estimates from experimental models | David Asher, MD, OBRR, CBER |
| 11:15 | Review of TSE clearance in FVIII product manufacturing | Dorothy Scott, MD, OBRR, CBER |
| 11:30 | FVIII product usage in clinical settings | Mark Weinstein, PhD, OBRR, CBER |

**AGENDA**

**TSEAC Agenda, October 31, 2005, (continued)**

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| 11:45 | Open Public Hearing (30 min) |
| 12:15 | Lunch |
| 1:15 | Committee discussion and recommendations |

**Topic 2: Labeling Claims for Filters Intended to Remove TSE Infectivity from Blood Components**

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| 2:45 | Prospects for reduction or removal of TSE agent infectivity from blood components by filtration and criteria for allowing claims: Introduction | Jaroslav Vostal, MD, PhD, OBRR, CBER |
| 3:00 | Evaluation of prion reduction filters | Marc Turner, MB ChB, PhD, FCRP(Lond) University of Edinburgh |
| 3:10 | Performance of Pall Corporation Leukoreduction filters on TSE infectivity of blood components: experimental studies and European experience | Dr. Sam Coker, Pall Corporation |
| 3:30 | Selection and performance of resin-bound ligands for removal of TSE infectivity from plasma | Robert Rohwer, PhD, PRDT (with ProMetic and ARC), Rockville MD |
| 3:50 | Other industry/academic filter/chromatography developer | Dr. Ralph Zahn, CEO Alicon AG, Schlieren, Switzerland |
| 4:10 | **Open Public Hearing** | |
| 4:40 | Committee discussion and recommendations | |
| 5:30 | Adjourn | |