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

8:00 a.m.	Administrative Remarks	William Freas, PhD, CBER, Executive Secretary TSEAC
8:10	Opening Remarks	Suzette Priola, PhD, NIAID, NIH, Chairperson TSEAC

Informational Presentations

8:15	Update on US and worldwide BSE status	Lisa Ferguson, DVM, APHIS, USDA
8:30	Criteria for considering label claims of effective decontamination for surgical instruments exposed to TSE agents: discussions of a recent FDA Device Panel	Sheila Murphey, MD, or other, CDRH
8:45	Update on vCJD in UK and other countries: estimates of prevalence	Azra C. Ghani, PhD, London School of Hygiene and Tropical Medicine Richard Knight, MD UK, Director, CJD Surveillance Unit, Edinburgh
9:45	Questions for speakers	
10:15	Break	

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

10:35	Variant CJD risk associated with human plasma derivatives: Introduction and overview of risk model	Steven Anderson, PhD, OBE, CBER
10:50	Prevalence estimates for vCJD in the UK	David Asher, MD, OBRR, CBER
11:05	Modeling risk of vCJD in US donors – residual risk and efficiency of donor deferral	Alan Williams, PhD, OBRR, CBER
11:20	VCJD infectivity of plasma – estimates from experimental models	David Asher, MD, OBRR, CBER
11:35	Review of TSE clearance in FVIII product manufacturing	Dorothy Scott, MD, OBRR, CBER
11:50	FVIII product usage in clinical settings	Mark Weinstein, PhD, OBRR, CBER
12:05	Summary of FDA proposals for FVIII risk assessment input parameters	Steven Anderson, PhD, OBE, CBER
12:20	Open Public Hearing	
1:00	Lunch	
2:00	Committee discussion and recommendations	

TSEAC Agenda, October 31, 2005, (continued)

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

3:00	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
3:15	Performance of Pall Corporation Leukoreduction filters on TSE infectivity of blood components: experimental studies and European experience	Pall Corporation representative
3:35	Selection and performance of resin-bound ligands for removal of TSE infectivity from plasma	Robert Rohwer, PhD, PRDT (with ProMetic and ARC), Rockville MD
3:55	Other industry/academic filter/chromatography developer	Alicon AG, Schlieren, Switzerland, representative
4:15	**Open Public Hearing**	
4:45	Committee discussion and recommendations	
5:30	Adjourn	