

DRAFT AGENDA 01/25/05
FOOD AND DRUG ADMINISTRATION
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE

February 8, 2005
Hilton Hotel
8727 Colesville Road
Silver Spring, MD

- 8:00 a.m. Administrative Remarks (10')
- 8:10 Opening Remarks
Chairperson (10')
- 8:30 Informational Presentation
Update on BSE surveillance in the U.S. (10') Lisa Ferguson, DVM, USDA
- 8:40 **Topic # 1 - Possible vCJD Risk from Investigational Coagulation Factor XI Manufactured in the 1990's from Plasma of Donors Residing in the United Kingdom**
- A. Introduction (10') M. Weinstein, Ph.D., OBRR, FDA
 - B. Elements of TSE risk assessments and risk assessment for U.K. FXI (45') S. Anderson, Ph.D., OBE, FDA
 - C. Current public health recommendations on management of surgical instruments used on patients with TSE or TSE risk (10') Lynne Schulster, Ph.D., CDC
- 9:45 Open public hearing (15')
- 10:00 Committee Discussion and Vote (40')
- 10:40 Break (20')
- 11:00 **Topic # 2 – Risk Assessment Models for Potential Risk of Exposure to variant Creutzfeldt-Jakob Disease (vCJD) Agent in Plasma Products**
- A. Introduction – rationale for risk assessments; question to committee (10') D. Scott, M.D., OBRR, FDA
 - B. Risk Assessment – U.K. plasma derivatives

Risk assessment methods and assumptions and U.K. actions based on risk assessment (40') Kate Soldan, Ph.D., and Anna Molesworth, MSc, U.K. Health Protection Agency

C. Preliminary Risk Assessment – U.S.

- i. Potential TSE clearance steps in U.S. products - FVIII, FIX, IGIV (10') D. Scott, M.D., OBRR, FDA
- ii. Risk Assessment Model for U.S. plasma derivatives (40') Steve Anderson, Ph.D., OBE, FDA

12:40 Questions for speakers (10')

12:50 Lunch

1:50 Open Public Hearing (40')

2:30 p.m. Committee Discussion and Vote (45')

3:15 Break

3:25 **Topic # 3 – Potential Deferral of Blood and Plasma Donors for History of Transfusion in European Countries**

- A. Introduction (10') A. Williams, Ph.D., OBRR, FDA
- B. Epidemiology of vCJD in France and risk assessments for blood and plasma derivatives (25') Dr. Jean-Philippe Brandel, Neurologist, Epidemiosurveillance Network
- C. Estimates of blood-borne vCJD risk in the U.K. and other European populations (20') Sheila M. Bird, M.A., Ph.D, Medical Research Council Biostatistics Unit, Institute of Public Health, Cambridge University, UK
- D. Risks and benefits of deferring donors transfused in France and other European countries: potential impact on blood and plasma supplies, and presentation of question for the committee (20') A. Williams, Ph.D.

4:40 Open public hearing (20')

5:00 Committee Discussion and Vote (35')

5:35 p.m. Adjourn