

AGENDA

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
- 8:10 Opening Remarks
Suzette Priola, Ph.D., Chairperson
- 8:20 Informational Presentation

Update on BSE surveillance in the U.S., Lisa Ferguson, DVM, USDA
- 8:30 **Topic # 1 - Possible vCJD Risk from Investigational Coagulation Factor XI Manufactured before 1998 from Plasma of Donors Residing in the United Kingdom**
- A. Introduction (10'), Mark Weinstein, Ph.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. Risk assessment for U.K. FXI (45'), Steven. Anderson, Ph.D., OBE, FDA
 - D. Current public health recommendations on management of surgical instruments used on patients with TSE or TSE risk (10'), Lynne Schulster, Ph.D., CDC
- 10:15 Questions for Speakers
- 10:25 Open Public Hearing
- 10:40 Break
- 10:50 a.m. Committee Discussion and Vote

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11:30 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’) Dorothy Scott, M.D., OBRR, FDA
- B. Preliminary Risk Assessment – U.S.
 - 1. Potential TSE clearance steps in U.S. products - FVIII, FIX, IGIV (10’), Dorothy Scott, M.D., OBRR, FDA
 - 2. Risk Assessment Model for U.S. plasma derivatives (40’) Steve Anderson, Ph.D., OBE, FDA

12:30 p.m. Questions for Speakers

12:40 Lunch

1:40 Open Public Hearing

2:10 Committee Discussion and Vote

3:05 Break

3:15 Topic # 3 – Potential Deferral of Blood and Plasma Donors for History of Transfusion in European Countries

- A. Introduction (10’), Alan 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 questions for the committee (20’), Alan Williams, Ph.D.

4:30 Open Public Hearing

4:50 Committee Discussion and Vote

5:35 p.m. Adjourn