

TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES

ADVISORY COMMITTEE

September 18-19, 2006

REFERENCES

Topic I: Experimental Clearance of Transmissible Spongiform Encephalopathy Infectivity in Plasma-derived Factor VIII Products

1. Foster PR. Removal of TSE agents from blood products. *Vox Sanguinis* 2004; 87 (Suppl. 2): 7-10.
2. Lee DC et al. A direct relationship between the partitioning of the pathogenic prion protein and transmissible spongiform encephalopathy infectivity during the purification of plasma proteins. *Transfusion Complications* 2001; 41: 449-455.

Topic II: Possible Criteria for Approval of a Donor Screening Test for vCJD

1. Chesebro, B. Introduction to the transmissible spongiform encephalopathies or prion diseases. *British Medical Bulletin* 2003; 66:1-20.
2. Will RG et al. A new variant of Creutzfeldt-Jakob disease in the UK. *Lancet* 1996; 347: 921-25.
3. World Health Organization. WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies. 2006: 1-78.
4. FDA "Draft Guidance for Industry: Amendment (Donor Deferral for Transfusion in France Since 1980) to 'Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products,' " August 2006; <http://www.fda.gov/cber/gdlns/cjdfrance.htm>.
5. FDA Quick Summary for the TSEAC meeting, October 31, 2005; <http://www.fda.gov/ohrms/dockets/ac/05/minutes/2005-4189M.pdf>

The complete meeting transcript is available at:

<http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4189t1.htm>

6. FDA Quick Summary for the TSEAC meeting, February 12-13, 2004; http://www.fda.gov/ohrms/dockets/ac/04/minutes/4019m1_quick%20summary.pdf

The complete meeting transcript is available:

http://www.fda.gov/ohrms/dockets/ac/04/minutes/4019m1_quick%20summary.pdf