

**List of Materials in the FDA Briefing package
for the TSEAC/VRBPAC Advisory Committee Meeting on July 27, 2000**

1. Transmissible Spongiform Encephalopathies Advisory Committee and Vaccines and Related Biological Products Advisory Committee, July 27, 2000 – Issue, Background, Charge, Questions, and References
2. Asher, D. M.: The Transmissible Spongiform Encephalopathy Agents: Concerns and Responses of United States Regulatory Agencies in Maintaining the Safety of Biologics, in Brown, F Griffiths E, Horaud F, Schild GS (eds): A Celebration of 50 Years of Progress in Biological Standardization and Control at WHO. Dev Biol Stand. Basel, Karger, 1999, vol 100, pp 103-118
3. MMWR, Vol. 48, No. 12: Achievements in Public Health, 1900 – 1999; Impact of Vaccines Universally Recommended for Children – United States, 1900 –1998
4. (Chart) Recommended Childhood Immunization Schedule, United States, January – December 2000 – Approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP)
5. Tan, Litjen; Michael A. Williams; Mohamed Khaleem Khan; Hunter C. Champion; and Nancy H. Nielsen for the Council on Scientific Affairs, American Medical Association: Risk of Transmission of Bovine Spongiform Encephalopathy to Humans in the United States, Report of the Council on Scientific Affairs, in JAMA, June 23/30, 1999 – Vol 281, No. 24
6. Bader F, G Davis, M Dinowitz, B Garfinkle, J Harvey, R . Kozak, A Lubiniecki, M Rubino, D Schubert, M Wiebe, G Woollett: Assessment of Risk of Bovine Spongiform Encephalopathy in Pharmaceutical Products
7. Listing of Specified Risk Materials: A Scheme for Assessing Relative Risks to Man; Opinion of the Scientific Steering Committee adopted on 9 December 1997
8. Preliminary Opinion of the Scientific Steering Committee on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR), 25 May 2000
9. Opinion, Oral Exposure of Humans to the BSE Agent: Infective Dose and Species Barrier. Adopted by the Scientific Steering Committee at its Meeting of 13-14 April 2000 Following a Public Consultation via Internet between 6 and 27 March 2000
10. The European Agency for the Evaluation of Medicinal Products Human Medicines Evaluation Unit, Committee for Proprietary medicinal Products (CPMP): Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products, London, 21 April 1999

11. Letter from Gerald V. Quinnan, Jr. Acting Director, FDA Center for Biologics Evaluation and Research, "Dear Biologic Product Manufacturer," 3 May 1991
12. Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals, FDA/Center for Biologics Evaluation and Research (CBER), July 12, 1993
13. Letter from Jane Henney, M.D., Deputy Commissioner for Operations, FDA, to Manufacturers of FDA- Regulated Products, December 17, 1993
14. Letter from Michael A. Friedman, Deputy Commissioner for Operations, FDA, to Manufacturers of FDA-Regulated Drug/Biologic/Device Products, May 9, 1996
15. Letter from Kathryn C. Zoon, Director, FDA Center for Biologics Evaluation and Research, to Manufacturers of Biological Products, April 19, 2000
16. Federal Register, Vol. 63, No. 3, Department of Agriculture, Animal and Plant Health Inspection Service, 9 CFR Parts 94 and 96, Restrictions on the Importation of Ruminants, Meat and Meat Products From Ruminants, and Certain Other Ruminant Products, January 6, 1998
17. Additional Reading (a listing)
18. Orenstein, Walter A., Alan R. Hinman, Lance E. Rodewald: Chapter 42, Public Health Considerations – United States, in Public Health and Regulatory Issues
19. Will, R. G.: New Variant Creutzfeldt-Jakob Disease, in Brown F, Griffiths E, Horaud F. Petricciani, JC (eds): Safety of Biological Products Prepared from Mammalian Cell Culture, Dev Biol Stand. Basel, Karger, 1998, vol 93, pp 79-84
20. Brown, Paul and Raymond Bradley: 1755 and all that: a historical primer of transmissible spongiform encephalopathy, in BMJ, Vol 317, 19-26 December 1998
21. Will R G, J W Ironside, M Zeidler, S N Cousens, K Estibeiro, A Alperovitch, S Poser, M Pocchiari, A Hofman, P G Smith: A new variant of Creutzfeldt-Jakob disease in the UK, in The Lancet, Vol 347, April 6, 1996