

## BRIEFING MATERIALS FOR TOPIC 1

The following briefing materials are provided for Topic 1 of the October 25 & 26 meeting of the TSE Advisory Committee:

1. US Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeld-Jakob Disease (CJD) and Variant Creutzfeld-Jakob Disease (vCJD) by Blood and Blood Products, DRAFT GUIDANCE, August 2001.
2. Summary and Rationale for this Draft Guidance
3. USDA Letter dated October 5, 2001 to U.S. Importers, Brokers, and Other Interested Parties; Subject: Clarification of the Prohibition of the Importation of all Ruminant Meat, Meat Products and Other Ruminant Protein Products from Japan due to Bovine Spongiform Encephalopathy (BSE).

4. References:

Foster, P.R., Prions and Blood Products. *Ann. Med.* 2000; 32:501-513

Lee, D.C., 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*, 2001; 41:499-455.