

DRAFT AGENDA (revised 10/22/01)

FOOD AND DRUG ADMINISTRATION

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE**

Holiday Inn
Kennedy Grand Ballroom (Fourth Floor)
8777 Georgia Avenue, Silver Spring, MD

October 25 & 26, 2001

FIRST DAY, Thursday, October 25, 2001, OPEN SESSION

8:00 a.m. Administrative Remarks,
William Freas, Ph.D., Executive Secretary

8:10 Opening Remarks
David Bolton, Ph. D., Committee Chairman

TOPIC 1. FDA's Draft Guidance on Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by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 (published in the Federal Register on August 29, 2001, <http://www.fda.gov/cber/gdlns/cjdvcjd.htm>)

8:15 a.m. Topic Overview
Dr. Dorothy Scott, M.D., OBRR, FDA

8: 35 Update: Current State of the Blood Monitoring Project and Plans to Extend Monitoring to the Supply of Plasma Derivatives and their Recombinant Analogs
Stephen D. Nightingale, M.D.
Executive Secretary, DHHS Advisory Committee on Blood Safety and Availability

8:45 Update: DHHS Meeting held on September 24, 2001
Stephen D. Nightingale, M.D.
Executive Secretary, DHHS Advisory Committee on Blood Safety and Availability

TSEAC AGENDA. Thursday, October 25, 2001, OPEN SESSION (continued)

8:55 a.m. Update: Anticipated Implementation of New Donor Deferral Policies

Celso Bianco, M.D.
Executive Vice President
America's Blood Centers

Ms. Jacquelyn Fredrick
Senior Vice President
Biomedical Services and COO Donor Enterprise Unit
American Red Cross

Robert Jones, M.D.
President
New York Blood Center

G. Michael Fitzpatrick, Ph.D.
Col, MS, USA
Director
Armed Services Blood Program Office

9: 20 Open Public Hearing

9:50 Committee Discussion

10:20 a.m. Break

TOPIC 2. Discussion of Amino Acid Sourcing and Production, and the Theoretical Risk of Transmission of the BSE Agent Through Their Use in Biopharmaceutical Products

10:30 a.m. Topic Introduction and Overview
Dr. Gerald Feldman, OTRR, CBER

10:50 Degussa-Rexim's Amino Acid Production Process
Mr. Gerard Richet
R&D Director, Deputy Plant Manager
Degussa-Rexim, France

11:20 Ajinomoto's Amino Acid Production Process
Mr. Mike McLean
Quality Assurance Director, NC Plant

11:35 Closed Session

TSEAC AGENDA. Thursday, October 25, 2001, OPEN SESSION (continued)

- 12:00 p.m. Lunch
- 1:00 Open Session - Open Public Hearing
- 1:30 Committee Discussion and Votes
- 3:00 Adjourn for the day

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SECOND DAY, Friday, October 26, 2001

TOPIC 3: Bovine Brain, Spinal Cord, and Other Neurological Tissue in Foods, Drugs, and Cosmetics for Human Use

- 8:00 a.m. Overview and Background
 Dr. Robert Brackett, CFSAN, FDA
- 8:10 Opportunities for Contamination of Edible Products in a Slaughter
 Plant with the BSE Agent
 William James, D.V.M.
 Director, Food Animal Sciences Division
 Office of Public Health & Science
 FSIS , USDA
- 8:50 Presentation of Questions to the Committee
 Dr. Robert Brackett, CFSAN, FDA
- 9:00 Committee Discussion
- 10:05 Break
- 10:20 Open Public Hearing
- 10:50 Committee Discussion and Votes
- 12:50 Open Public Hearing
- 1:00 p.m. Adjourn for the day