

# **AGENDA**

## **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 FDA's Draft Guidance on Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by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 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

# FOOD AND DRUG ADMINISTRATION

## TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE

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 Preventing 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