# AGENDA

# FOOD AND DRUG ADMINISTRATION

# TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE

Holiday Inn - Gaithersburg
2 Montgomery Village Avenue
Gaithersburg, Maryland 20879
June 1-2, 2000

FIRST DAY, Thursday, June 1, 2000

| | |
|---|---|
| 8:30 a.m. | Opening<br>**P. Brown, MD, Committee Chairman** |
| 8:35 a.m. | Administrative Remarks<br>**W. Freas, PhD, Executive Secretary, TSEAC, FDA** |
| 8:45 a.m. | Introductory Remarks<br>**B. Schwetz, DVM, PhD**<br>Acting Deputy Commissioner for Food and Drugs<br>Senior Advisor for Science, FDA |

## Topic 1. DEFERRAL OF BLOOD DONORS BASED UPON FOOD-BORNE EXPOSURE TO BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) AGENT: COMPARISON OF POTENTIAL EXPOSURE IN VARIOUS COUNTRIES

| | |
|---|---|
| 8:50 a.m. | Background, charge and questions<br>**D. Asher, MD**<br>Office of Blood Research and Review, CBER, FDA |
| 9:10 a.m. | BSE and vCJD in UK: update with EU CJD surveillance overview.<br>**R. Will, MD**<br>National Creutzfeldt-Jakob Disease Surveillance Unit, Western General Hospital, Edinburgh, Scotland, UK |
| 9:30 a.m. | BSE in France<br>**C. Ducrot, DVM, PhD**<br>Unité d'Epidémiologie Animale |

Saint-Genes-Champanelle, France

TSEAC AGENDA, June 1, 2000 (continued)

| | |
|---|---|
| 9:50 a.m. | vCJD in France: epidemiology, modeling and predictions<br>**A. Alpérovitch, MD, MSc**<br>Hopital de la Salpetriere<br>Paris, France |
| 10:10 a.m. | BSE in Switzerland: History, surveillance, control efforts and agricultural policies<br>**D. Heim, DVM**<br>Swiss Veterinary Authority<br>Switzerland |
| 10:35 a.m. | CJD in Switzerland: Surveillance and public-health policy<br>**F. Montrasio, PhD**<br>University Hospital of Zurich<br>Institute of Neuropathology<br>Zurich, Switzerland |
| 10:55 a.m. | Break |
| 11:10 a.m. | Worldwide occurrence of BSE: USDA policies and reactions to recent OIE and EC assessments and actions<br>**L. Detwiler, DVM**<br>APHIS, USDA<br>Robbinsville, NJ |
| 11:30 a.m. | New-variant CJD and Blood Safety in the European Union. Potential human exposure to BSE, national and EC surveillance activities and public policies concerning blood<br>**J. Löwer, MD**<br>Paul Ehrlich Institute<br>Langen, Germany<br>Directorate General XXIV<br>(Consumer Policy & Consumer Health Protection)<br>European Commission<br>Brussels, Belgium |
| 11:50 a.m. | Questions and Discussion |
| 12:30 p.m. | Lunch |

1:30 p.m. Open Public Hearing

TSEAC AGENDA, June 1, 2000 (continued)

2:00 p.m. Surveillance of nvCJD and potential human exposure to BSE agent in the Republic or Ireland
**S. Molloy, MB, BCh, BAO, MRCPI**
Clinical CJD Surveillance Registrar
St. Vincent's Hospital
Dublin, Ireland

2:10 p.m. A model quantitative assessment of the risk of vCJD in Canadian travelers to the UK and France
**A. Giulivi, MD, FRCPC**
Laboratory Centre for Disease Control
Ottawa, Ontario, Canada

2:30 p.m. Reanalysis of survey of US blood donors conducted by the American Red Cross, American Association of Blood Banks, America's Blood Centers, and the National Heart, Lung, and Blood Institute: European travel outside the UK
**K. Watanabe, MS**
Senior Study Director
WESTAT INC
Rockville, Maryland

2:40 p.m. Implementation and effect of recent changes in deferral policies on US blood supply
**P. McCurdy, MD**
National Heart, Lung, and Blood Institute, NIH

2:45 p.m. Effect of implementation: UK deferral data
**M. Sullivan, MS, MPH**
Executive Director, National Blood Data Resource Center
Bethesda, MD

2:50 p.m. Open Public Hearing

3:10 p.m. Review of charge and questions
**D. Asher, MD**
Office of Blood Research and Review, CBER, FDA

3:15 p.m. Discussion

3:45 p.m. Break

| | |
|---|---|
| 4:00 p.m. | Further discussion and vote |
| 5:15 p.m. | Break for the day |

**FOOD AND DRUG ADMINISTRATION**

**TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE**

**Agenda (continued)**

SECOND DAY, Friday, June 2, 2000

8:30 a.m. Opening
**Paul Brown, MD, Committee Chairman**

8:35 a.m. Administrative Remarks
**William Freas, PhD, Executive Secretary, TSEAC, FDA**

**Topic 2. POSSIBLE EFFECTS OF LEUKOREDUCTION ON CJD RISK**

8:40 a.m. Background, charge and questions
**D. Asher, MD**
Office of Blood Research and Review, CBER, FDA

8:50 a.m. Leukoreduction of blood: Introduction, background, recent recommendations and prospects for implementation
**J-H Lee, MD**
Office of Blood Research and Review, CBER, FDA

9:10 a.m. Leukoreduction of blood: Techniques, results, and theoretical applications to TSE agents in blood
**J. Vostal, MD, PhD**
Office of Blood Research and Review, CBER, FDA

9:30 a.m. Infectivity of nucleated blood cells from experimentally infected rodents: possible role in the pathogenesis of TSE and implications for human blood
**F. Montrasio, PhD**
University Hospital of Zurich
Institute of Neuropathology
Zurich, Switzerland

| | |
|---|---|
| 9:50 a.m. | Leukoreduction of blood: experimental studies with blood infected with rodent-adapted scrapie and CJD agents. Possible implications for safety of human blood with regard to CJD and new-variant CJD<br>**R. Rohwer, PhD**<br>Medical Research Service, Veterans Administration and Maryland Health Care System and University of Maryland School of Medicine<br>Baltimore, Maryland<br><br>(P.W. Brown, MD, Committee Chairman, to comment) |
| 10:20 a.m. | Discussion |
| 10:30 a.m. | Break |
| 10:45 a.m. | Open Public Hearing |
| 11:15 a.m. | Review of charge and questions<br>**D. Asher, MD**<br>Office of Blood Research and Review, CBER, FDA |
| 11:20 a.m. | Discussion and vote |
| 12:15 p.m. | Lunch |
| 1:30 p.m. | Reconvene |

**Topic 3. UPDATE ON THE REGULATORY STATUS OF PROCESSED HUMAN DURA MATER**

| | |
|---|---|
| 1:30 p.m. | Update on the regulatory status of processed human dura mater<br>**C. Durfor, PhD**<br>Office of Device Evaluation, CDRH, FDA |
| 1:45 p.m. | Open Public Hearing |
| 2:00 p.m. | Adjourn |