AGENDA

FOOD AND DRUG ADMINISTRATION
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE

July 17 & 18, 2003
Holiday Inn Select
8120 Wisconsin Avenue
Bethesda, MD 20814

First Day, Thursday, July 17, 2003

8:00 a.m. Administrative Remarks
8:10 Opening Remarks
Dr. Suzette Priola, Chairperson

8:20 **Topic # 1 - Safety of Bovine Bone Gelatin in Oral and Topical Drugs, Food and Cosmetics**

Background and Introduction
Dr. Morrie Potter, CFSAN, FDA (15')
Questions to the Committee
Dr. Yuan-yuan Chiu, CDER, FDA (10')
Market Trend in United States
Mr. George Masson, President GMIA (20')
Manufacturing Process for Bone Gelatin – Industry Practices in United States
Dr. Michael Dunn, Vice President, Chairman of the Regulatory Committee, GMIA (20')
Manufacturing Process for Bone Gelatin – Industry Practices in Europe
Mr. Reinhard Schrieber, Chief Manufacturing Officer, Deutsche Gelatine-Fabriken Stoess AG, Gelita Group (20')

9:45 Break
10:00 Reports of Three GME Validation Studies on Bone Gelatin
Dr. Robert Sommerville, IAH Edinburgh, UK (60')
Risk Analysis of Infectivity
Dr. Ron Rogers, Health Canada, Ottawa (15')
USDA Gelatin Policy
Dr. Terry Morris, APHIS (20')
11:35 **Open Public Hearing**
11:55 **Committee Discussion and Voting**
12:25 p.m. Lunch

TSEAC AGENDA

First Day, Thursday, July 17, 2003 (continued)

1:25 p.m. **Topic # 2 - BSE in Canada**

Potential Exposure of Blood Donors in North America to the BSE Agent
Dr. Jay Epstein, Director, OBRR, CBER, FDA (5')
Review of Bovine Spongiform Encephalopathy in Canada (15')
Dr. Robert Hills, Health Canada, Ottawa

1:45 **Open Public Hearing**

2:15 **Committee Discussion**

Topics # 3 and # 4: General Introduction

TSEs and Decontamination of Medical Equipment and Facilities

2:45 TSEs, Decontamination and FDA Regulated Products
Dr. David M. Asher, OBRR, CBER, FDA (10')

2:55 Invited Speakers

Principles of TSE Inactivation: Validation and Use of Infectivity Assays and Assays for Abnormal Prion Proteins,
Dr. Robert Rohwer, Director Molecular Neurovirology Unit, VA Medical Center, Baltimore (20')
Review of Effective Decontamination of TSE Agents: Basis for WHO Recommendations,
Dr. David Taylor, SEDECON 2000, UK (30')

3:45 Questions for Previous Speakers

3:55 Reducing the Risk of CJD Transmission through Surgical Procedures: Experience in UK, (30')
Dr. Philippa Edwards, Principal Scientist, CJD Policy Team, UK
TSE Agents and Infection Control in Hospitals: Experience in USA
Dr. William Rutala, UNC (20')

4:45 Break

5:00 Preliminary Results: Infectivity of Air Emissions and Residues from Simulated Incineration of Scrapie Tissues
Capt. Edward Rau, Environmental Health Officer, NIH (30')
TSE Infectivity: Experience with Models for Validating Decontamination of Surfaces and Effects of Decontamination on Materials (30')
Drs. David M. Asher, CBER and Stanley Brown, CDRH

6:00 p.m. Adjourn

TSEAC AGENDA

Second Day, Friday, July 18, 2003

8:00 a.m. Administrative Remarks

8:10 **TSEs and Decontamination: Introductory Presentations** (continued)

A Model for Evaluating TSE Decontamination of Metal Objects: Recent Progress
Dr. C. Weissmann, MRC Prion Unit, Imperial Coll., London (30')

TSE Decontamination: Studies Relevant to Facility and Equipment Cleaning
Dr. Cristoph Kempf, Plasma Protein Therapeutics Association (PPTA) (15')

8:55 Topic # 3 – Reprocessing of Medical Devices, Contaminated or Potentially Contaminated with TSE agents

Introduction (10')
Ms. Lillian Gill, CDRH, Senior Associate Director for Science

Background: Validating Sterilization of Medical Devices (20')
CDR Martha O'Lone, Infection Control Devices Branch, CDRH

9:25 **Open Public Hearing**

10:20 BREAK

10:35 Presentation of Topic 3 Questions
Dr. Charles Durfor, CDRH, FDA

Committee Discussion and Voting on Topic 3 Questions

11:50 Lunch

12:50 Topic # 4 - Methods to Decontaminate Facilities and Equipment Used to Prepare Human Cells, Tissue & Cellular and Tissue-Based Products (HCT/Ps), and Human Blood Products, Including Plasma Derivatives, to Reduce the Theoretical Risk of Transmitting TSE Agents.

Methods used in Human Cells, Tissues & Cellular and Tissue-Based Product (HCT/P) Establishments
Dr. R. Solomon (10')

Methods used in Eye Banks
Ellen Heck, UT Southwestern Medical Center (10')

Methods used in Plasma Derivative Manufacturing
Dr. D. Scott, OBRR, CBER, FDA (10')

Decontamination Practices for Plasma Product Facilities
Dr. Christoph Kempf , PPTA (10')

Proposed PPTA-Sponsored Collaborative Study on Inactivation of TSE Agents with Sodium Hydroxide and Sodium Hypochlorite, commonly used to clean and decontaminate facilities and equipment in manufacture of plasma derivatives
Dr. Andrew Bailey, PPTA (15')

1:45 **Open Public Hearing** (30')

2:15 Presentation of Topic 4 Questions

Committee Discussion and Voting on Topic 4 Questions

4:15 p.m. Adjourn