DRAFT AGENDA
FOOD AND DRUG ADMINISTRATION
TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES
ADVISORY COMMITTEE

July 17 & 18, 2003
Holiday Inn Select
8120 Wisconsin Avenue
Bethesda, MD 20814
(revised 7/8/03)

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. Robert Hills, Health Canada, Ottawa (15')
USDA Gelatin Policy
Dr. Terry Morris, APHIS (20')
11:35 **Open Public Hearing (20')**
11:55 **Committee Discussion and Voting** (30')
12:25 p.m. Lunch

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

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

Review of Bovine Spongiform Encephalopathy in Canada (15')
Dr. Robert Hills, Health Canada, Ottawa
Potential Exposure of Blood Donors in North America to BSE Agent
Dr. Steven Anderson or Dr. Sonja Sandberg, OBE, CBER, FDA (15')

1:55 **Open Public Hearing** (30')

2:25 **Committee Discussion** (30')

Topics # 3 and # 4: General Introduction

TSEs and Decontamination of Medical Equipment and Facilities

2:55 TSEs, Decontamination and FDA Regulated Products
Dr. David M. Asher, OBRR, CBER, FDA (10')

3:05 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')
Reducing the Risk of CJD Transmission through Surgical Procedures: Experience in UK,
Dr. Philippa Edwards, Principal Scientist, CJD Policy Team, UK (30')
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

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Second Day, Friday, July 18, 2003

8:00 a.m. Administrative Remarks

8:10 **TSEs and Decontamination: Introduction** (continued)

A Model for Evaluating TSE Decontamination of Metal Objects: Recent Progress

Dr. Charles Weissmann, MRC Prion Unit, Imperial Coll., Lond (30')

TSE Decontamination: Validation Studies Relevant to Manufacturing Facilities and Equipment Cleaning

Dr. Cristoph Kempf, ZLB, Plasma Protein Therapeutics Association (PPTA) and U. of Bern, Switzerland (15')

9:10 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

9:40 Open Public Hearing (40')

10:20 BREAK (15)

Presentation of Topic 3 Questions (5')

Dr. Charles Durfor, CDRH, FDA

Committee Discussion and Voting on Topic 3 Questions (70')

11:50 Lunch

12:50 Topic # 4 - Methods to Decontaminate Facilities and Equipment Used to Prepare Human Cellular and Tissue Products (HCTP), 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. Ruth Solomon (10')

Methods used in Eye Banks

Ms. Ellen Heck, UT Southwestern Medical Center (10')

Methods used in Plasma Derivative Manufacturing

Dr. Dorothy Scott, OBRR, CBER, FDA (10')

Proposed Industry-Sponsored Collaborative Validation Study for TSE Clearance Methods Relevant to Facility and Equipment Cleaning for Plasma Derivatives

Dr. Andrew Bailey, Baxter Healthcare and PPTA (10')

1:30 Open Public Hearing (30')

2:00 Presentation of Topic 4 Questions (5')

Committee Discussion and Voting on Topic 4 Questions (70')

4:15 p.m. Adjourn