FOOD AND DRUG ADMINISTRATION

TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE

Holiday Inn
2 Montgomery Village Avenue
Gaithersburg, MD 20879
June 26-27, 2002

AGENDA

FIRST DAY, Wednesday, June 26, 2002

OPEN SESSION

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

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

Topic #1: Validation of Procedures to Prevent Contamination and Cross-Contamination with TSE Agents of Human Tissue Intended for Transplantation

8:15 a.m. **Introduction and Background—Current and Proposed FDA Regulations and Guidance pertaining to TSE and Human Cells, Tissues, and Cellular and Tissue-Based Products Intended for Transplantation**

Additional Donor Screening Measures (e.g., possible exclusion for age at death, death from head trauma)
R. Solomon, M.D., OBRR, FDA

8:45 a.m. **Risk Assessment: Models for Estimating the Risk of Transmitting TSE by Human Tissue Intended for Transplantation**
R. Taffs, Ph.D., OBRR, FDA

9:15 a.m. **Additional Testing Measures (e.g., potential value of post mortem transorbital frontal lobe needle biopsy)**
N. Hogan, M.D. Ph.D., University of Texas

Wednesday, June 26, 2002 (Open Session Continued)

Processing Controls

9:30 a.m. 1. **Implications of Batch Processing for Manufacture of Human Cells, Tissues and Cellular and Tissue-Based Products**

a. Experience with Human Dura Mater Allograft and Pituitary-Derived Hormones*:* Lessons for Other Human Tissues.
P. Brown, M.D., Senior Research Investigator, NINDS, NIH

b. **Experience of a Commercial Manufacturer of Pituitary-derived Hormone**
A. Eshkol, Ph.D., Senior Scientific Advisor, Serono International SA, Geneva

10:15 a.m. **BREAK**

10:30 a.m. 2. **Limiting Batch Size: Effects of Batch Size on Risk of Contamination with Infectious Agents**
T. Lynch, Ph.D., J.D., Clearant, Inc.

10:45 a.m. 3. **Single Donor Aseptic Recovery and Processing of Human Tissue**

a. **Potential for Cross-Contamination of Bone and Soft Tissue with Higher-Risk Tissues during Recovery**
P. Brown, M.D., NINDS, NIH, Bethesda, MD

b. American Association of Tissue Banks
D. Wilson, R.N., Chief Operating Officer, Community Tissue Services

c. Eye Bank Association of America
E. Heck, Director, Transplant Services Center, University of Texas,

11:30 a.m. 4. **Equipment and Instruments: TSE Agent Disinfection in Routine and Exceptional Situations**
R. Rohwer, Ph.D., VA Medical Center, Baltimore, MD

Wednesday, June 26, 2002 (Open Session Continued)

11:45 a.m.	**Process Validation for Conventional Agents** M. Farshid, Ph.D., OBRR, FDA
	Process Validation—Industry Presentations
12:00 p.m.	R. Hurwitz, MD, FACS, Interim President/CEO and Medical Director LifeNet, Virginia Beach, VA
12:15 p.m.	R. Russo, Executive Vice President and General Manager - International Osteotech Inc., Eatontown, NJ
12:30 p.m.	C. R. Mills, Ph.D., Vice President of Operations Regeneration Technologies, Inc., Alachua, FL
12:45 pm.	**LUNCH**
1:45 p.m.	**Experience with TSE Agent Clearance Studies in Experimental Models** R. Rohwer, Ph.D., VA Medical Center
2:15 p.m.	**OPEN PUBLIC HEARING**
3:15 p.m.	**Committee Discussion**
3:45 p.m.	**Questions to the Committee**
4:15 p.m.	**BREAK**

Topic #2: FDA Draft Guidance on Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products

4:30 p.m.	**Presentation of Draft Guidance** M. Greenwald, M.D., OBRR, FDA
5:00 p.m.	**Possible Effects on Tissue Supply** A. Williams, Ph.D., OBRR, FDA
5:15 p.m.	**Committee Discussion**
5:45 p.m.	**Adjourn for the day**

TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE

SECOND DAY, June 27, 2002, OPEN SESSION

Committee Updates:

8:30 a.m. **Update on Implementation of Revised Guidance on Blood Donor Deferrals for Risk of CJD and vCJD**

. **Introduction**
D. Scott, M.D., OBRR, FDA

8:45a.m. **Effects on Blood Supply**
Department of Health and Human Services
S. Nightingale, M.D., Executive Secretary,
Advisory Committee on Blood Safety
New York Blood Center
R. Jones, M.D., President
American Red Cross
P. Page, M.D., Senior Medical Officer
America's Blood Centers
C. Bianco, M.D., Senior Vice President
Department of Defense
R. Alford, Major, USAF, BSC
Deputy Director, Armed Services Blood Program
American Association of Blood Banks
K. Gregory, Director Regulatory Affairs

9:45 a.m. **OPEN PUBLIC HEARING**

10:30 a.m. **Studies of vCJD Infectivity in Blood of Experimental Mice**
L. Cervenakova, MD, PhD
The Jerome Holland Laboratory
American Red Cross

11:00 a.m. **Retention of TSE infectivity by Planova nanofilters as a function of spike composition**
L. Gregori, Ph.D.
Laboratory of Molecular Neurovirology
VA Medical Center and University of Maryland School of Medicine

11:30 a.m. **Committee Discussion**

12:00 p.m. **ADJOURN**